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Part III

Department of Agriculture

Animal and Plant Health Inspection Service

9 CFR Parts 1, 2, and 3
Animal Welfare; Proposed Rules

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 1

[Docket No. 88-013]

Animal Welfare—Definition of Terms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This is a request for supplemental comments on the narrow issue of the interrelationship between Part 1 of the Animal Welfare Act regulations and our proposal to amend Part 3 of the regulations. We are proposing to amend Part 1 of the regulations concerning animal welfare, in order to update, clarify and expand the list of definitions. These changes are intended to inform the public of the scope of the regulations and to facilitate enforcement of them. These changes, many of which are required by amendments enacted on December 23, 1985, to the Animal Welfare Act (7 U.S.C. 2131, *et seq.*), complement changes we are proposing to make to Part 2 of the regulations concerning animal welfare (Regulations) and to Part 3 of the regulations concerning animal welfare (Standards).

DATES: We will consider written comments addressing only the interrelationship of Parts 1 and 2 of the regulations with the proposed standards of Part 3, as explained in greater detail in the Supplementary Information which follows, that are postmarked or received on or before May 15, 1989.

ADDRESS: Send an original and three copies of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 1000, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 88-013. Comments received may be inspected at the APHIS Public Reading Room, Room 1141, U.S. Department of Agriculture, 14th and Independence Avenue SW., Washington, DC, 8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. R.L. Crawford, Director, Animal Care Staff, REAC, APHIS, USDA, Room 268, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7833.

SUPPLEMENTARY INFORMATION:

Background

This document would amend and expand 9 CFR Part 1, entitled "Definition of Terms" which provides the definitions for the terms used in the regulations in 9 CFR Part 2, and the standards in 9 CFR Part 3 for the humane handling, care, treatment, and transportation of regulated animals used for research or exhibition purposes, sold as pets, or transported in commerce. The Definitions, Regulations, and Standards are established pursuant to the authority in the Animal Welfare Act, as amended (7 U.S.C. 2131, *et seq.*) (the Act). This law requires the Secretary to promulgate regulations and standards governing the humane handling, housing, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, operators of auction sales, carriers, and intermediate handlers. The standards and regulations must include minimum requirements with respect to handling, housing, feeding, sanitation, veterinary care, and other matters specified in section 13 of the Act (7 U.S.C. 2143). Upon publication of a final rule, these definitions will provide specific meanings for the most important terms used in the regulations and standards.

In a document published in the Federal Register on March 31, 1987 (52 FR 10292-10298), we proposed to amend the Animal Welfare regulations, 9 CFR Parts 1 and 2, "Definition of Terms" and "Regulations," to comply with the 1985 amendments to the Animal Welfare Act, and to expand, clarify, and revise the current regulations.

Comments were solicited concerning both proposals for a 60-day period ending June 1, 1987. This period was twice extended and ended on August 27, 1987. We received a total of 7,857 comments: 1,438 were from the research community; 987 were from dealers and exhibitors; and 5,432 were from members of the public, including humane organizations and animal welfare societies. All of the comments that were timely received were considered. Those raising objections or suggesting changes to the proposed definitions are discussed below. Comments received after the close of the comment period have not been considered.

In response to the numerous comments received, we determined that certain changes to our proposal are necessary. These changes, discussed below, have been incorporated in this revised rule. In addition, many of the comments we received in response to our March 31, 1987 proposal to amend Part 2 suggested that certain additional terms should be defined. We have also determined that certain terms appearing in the proposed rule to amend Part 3 require definition so that the public can understand them. We are therefore adding several definitions, as discussed below, to make the regulations in Parts 2 and 3 easier to understand, thereby increasing compliance and making them more effective.

Each definition addressed below has been given its own heading to assist the reader in locating a particular term. Comments concerning the proposed definitions as a whole are discussed first under the heading, "General."

Supplemental Request for Comments on Interrelationship of Parts 1, 2, and 3 of the Animal Welfare Regulations

We received 334 comments (309 from members of the research community and 25 from members of the general public) suggesting that we revise the proposed rules for Parts 1 and 2, "Definition of Terms" and "Regulations," and publish a second proposal in the Federal Register for public comment. We also received 445 comments (400 from members of the research community and 45 from members of the general public) suggesting that we revise the proposals for Parts 1 and 2 and publish them along with our proposal for standards for the exercise of dogs and for a physical environment to promote the psychological well-being of nonhuman primates. These specific standards are mandated by the 1985 amendments to the Act.

We have determined to respond to the comments we received addressing the proposed rules, and to publish revised rules for Parts 1 and 2 in the same issue of the Federal Register as our proposal to amend Part 3 of the regulations, titled "Standards." The revised rules reflect our consideration of the nearly 8,000 comments received, our experience in administering and enforcing the regulations, and our ongoing consultation with the U.S. Department of Health and Human Services and other interested agencies. It is our present determination that upon their adoption as final rules, the revised provisions of Parts 1 and 2 will conform with the requirements of the Animal Welfare Act, as amended.

Accordingly, we are publishing Parts 1 and 2 at this time, revised from our initial proposal, as explained in detail below, to assist the public in reviewing the proposed standards for Part 3. At the urging of many commenters, we are publishing the revised rules for Parts 1 and 2 as a proposal, for the sole purpose of soliciting comments on the narrow

issue of the interrelationship of the definitions and regulations in Parts 1 and 2 with the standards we are proposing in Part 3. The public is therefore invited to comment exclusively on this issue. We will not consider comments going beyond this issue.

General

We received 307 comments (281 from the research community, 25 from members of the general public, and 1 from an exhibitor) generally endorsing the definitions as proposed but suggesting that some require clarification or revision. We received 74 comments (72 from the research community and 2 from dealers) citing the need for reorganization of the proposed regulations as a whole (Parts 1 and 2), and for clarification in general. We have further clarified or revised those definitions as necessary, based upon the comments received.

Sixteen commenters from the research community felt generally that the definitions as proposed are too rigid and specific. We disagree. The proposed definitions must be specific to be meaningful to the persons subject to the Act and to the regulations, and to enable those persons to comply with the regulations. Except as explained below, the provisions of the initial proposed rule for Part 1 continue to be included in this revised rule based on the reasons set forth in that proposal.

Administrative Unit

The 1985 amendments to the Act require that each research facility establish an Institutional Animal Committee composed of not fewer than three members (7 U.S.C. 2143(b)(1)). Of the three members, at least one must be a doctor of veterinary medicine and at least one must not be affiliated in any way with the facility, other than as a member of the Committee. Section 13(b)(1)(C) of the Act provides that "in those cases where the Committee consists of more than three members, not more than three members shall be from the same administrative unit of such facility." (7 U.S.C. 2143(b)(1)(C).) In our March 31, 1987, proposal to amend Part 2 of the regulations, we proposed requirements in § 2.35 for the composition of the Committee. As mandated by the Act, proposed § 2.35(a)(6) provided that "[i]f the Committee consists of more than three members, not more than three members shall be from the same administrative unit of such facility; * * *" This provision is included in Part 2, as revised, published elsewhere in this issue of the **Federal Register**. (See companion docket No. 88–014.)

We received 465 comments (440 from the research community and 25 from members of the general public) requesting that the term "administrative unit" be defined. We are therefore including the following definition of that term:

> The organizational or management unit at the departmental level of a research facility.

For universities, corporations, and other research facilities, departments such as the Department of Medicine, Department of Research and Development, the Department of Chemistry, the Department of Pharmacology, the Department of Psychology, and the Department of Zoology would each be an administrative unit for purposes of Committee membership.

Ambient temperature

Three commenters stated that the proposed definition of the term "ambient temperature" is vague. Except for the addition of the word "air" before "temperature" the proposed definition has been in the regulations since 1970. We have not learned of any problems in understanding and applying this term during the past 18 years. In the absence of any problems arising from the definition of "ambient temperature" the definition remains as initially proposed.

Animal; Dog; Cat

We proposed to define the term "animal" as follows:

> any live or dead dog, cat, nonhuman primate (monkey, ape), guinea pig, hamster, rabbit, or any other warmblooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes: Birds, rats and mice bred for use in research, and horses and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.

This proposed definition prompted numerous comments, although the only substantive change we proposed to make in the current definition was to delete the phrase "which is domesticated or raised in captivity or which normally can be found in the wild state." This qualifying phrase modifies "any other warmblooded animal" in the current definition. We received 318 comments (293 from the research community and 25 from members of the general public) generally endorsing the proposed definition. More than 1,000 commenters (991 from the general public, 24 from the research community, and 2 dealers) stated that the definition should encompass all warmblooded animals, including rats, mice, birds, and farm animals. We received 322 comments (297 from the research community and 25 from members of the general public) stating their agreement with excluding laboratory rats and mice from the definition.

When first enacted in 1966 the Act defined the term "animal" as meaning "live dogs, cats, monkeys (nonhuman primate mammals), guinea pigs, hamsters, and rabbits." In 1970 the definition was amended to include other warm-blooded animals, and to specifically exclude horses "not used for research purposes" and other farm animals when used for agricultural purposes.

Since the Animal Welfare regulations were amended in 1972 to incorporate the 1970 amendments to the Act, the definition of "animal" has included the six kinds of animals listed above and "any other warmblooded animal, which is domesticated or raised in captivity or which normally can be found in the wild state, and is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet." The definition of "animal" has excluded "birds, rats and mice, and horses and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber."

We are not changing our definition of "animal" to include horses not used for biomedical research, and other farm animals when used for agricultural purposes, because the Act does not give us authority to include them (7 U.S.C. 2132(g)). Neither are we changing our definition of "animal" to include birds, rats and mice. We do have the authority to regulate these animals, though except for wild rats and mice, we have never covered them in our regulations. However, in response to the comments we received, we are considering developing regulations and standards for them. Development of new regulations and standards requires detailed analysis of the issues involved, followed by drafting of proposed rules. It is a time-consuming process. We do not believe it would be in the best interests of animal welfare in general if we were to delay promulgating the

regulations we have proposed. We also do not believe Congress intended that we delay promulgating regulations concerning other animals pending the possible development and drafting of regulations and standards for birds, rats and mice. Therefore, we are not changing our proposed definition of "animal" to include birds, rats and mice in this rule. If we propose regulations and standards governing birds, rats and mice, we will also propose to amend the definition of "animal" to include them. We do want to note that wild rats and mice are covered by our proposed definition, though laboratory-bred rats and mice are not. We are revising the definition of "animal" to clarify this point.

We received 303 comments (278 from the research community and 25 from members of the general public) suggesting that we delete the reference to "all warmblooded animals" in the preamble statement that "[a]ll warmblooded animals are covered by the Act," because it is misleading. Although the preamble to a proposed rule does not have the force of law, we agree that this reference could have been more precise since the Act excludes certain warmblooded animals, such as horses and farm animals, not used for research purposes.

We received 103 comments (102 from the research community and 1 from a member of the general public) stating that the definition of "animal" should not include reference to "dead" animals, and 5 comments from the research community suggesting that when the regulations are meant to include dead animals the term should be so qualified. The Act defines "animal" as both live or dead animals (7 U.S.C. 2132(g)), and accordingly the Animal Welfare regulations have defined "animal" in this manner since 1972. The word "dead" was added to the definition of "animal" as part of the 1970 amendments to the Act, due to the mistreatment of animals obtained for euthanasia and preparation as laboratory specimens. Inclusion of dead animals in the regulations is determined to be necessary based upon our experience in enforcing the regulations, to prevent abuse of these animals. We agree that many of the standards proposed in companion docket number 87-004, Part 3—"Standards," published elsewhere in this issue of the **Federal Register**, would not apply to dead animals, and we have added footnotes to proposed Subparts A and D in Part 3, to make clear that those standards would refer to live animals unless otherwise specified.

We received 50 comments from the research community stating that the definition of "cat" likewise should not include reference to dead cats. We disagree, since the Act defines animal as any "live or dead dog, cat, * * *" and since our experience indicates the necessity to include this protection in the regulations for the reasons explained above. No change is made to the definition of "cat" in this rule.

Thirty-two commenters from the research community stated that the definition of "dog" should not include the word "dead." For the same reasons provided above regarding animals and cats, no change is made in the definition of "dog" in the rule.

We received 2 comments from the research community stating that all rodents, including gerbils and guinea pigs, should be excluded from the regulations. Guinea pigs have been included in the Act since it was first enacted in 1966. At that time the Act covered 6 kinds of animals: Dogs, cats, guinea pigs, hamsters, rabbits, and nonhuman primates. Gerbils became a regulated species when the 1970 amendments to the Act expanded the definition of "animal" to include "such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use for research, testing, * * *." We do not have the authority to remove these animals from the coverage of the regulations. No change is made to the definition of "animal" based upon these comments.

Thirty-one commenters from the research community stated that the definition of "animal" should refer to "nonhuman primates (monkeys and apes)" instead of to "monkey (nonhuman primate mammal)." We agree that use of the term "nonhuman primates" is more precise because all nonhuman primates, not just monkeys and apes, are covered by the regulations. We are revising the definition of "animal" to reflect this change. Except for this revision, the definition of "animal" remains as initially proposed.

Attending veterinarian; Licensed veterinarian

The definition of "attending veterinarian" as initially proposed would mean:

> a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, has received training and/or experience in the care and management of the species being attended, and who has direct or delegated responsibility for activities involving animals at a registered or licensed facility. The veterinarian must be accredited by the U.S. Department of Agriculture in accordance with regulations issued under the Animal Welfare Act.

We received 548 comments (519 from the research community, 2 from dealers, 1 from an exhibitor, and 26 from members of the general public) stating that reference to USDA accreditation should be deleted from the definition of "attending veterinarian" and that the requirement to be accredited by USDA be clarified vis-a-vis state licensure requirements. Eleven commenters from the research community suggested that we use a term other than "accredited."

There is no requirement for state licensure in the definition. Our use of the term "accredited" was intended as a means of ensuring that attending veterinarians have training and/or experience in animal welfare, including humane handling, care, and treatment of laboratory animals, in order to provide adequate veterinary care in accordance with the Animal Welfare regulations. We agree that another term, such as "registered," should be substituted for the term, "accredited," to avoid confusion with the Accreditation of Veterinarian regulations in 9 CFR Parts 160, 161, and 162. The Department is in the process of developing standards for "accreditation" (or "registration") under the Animal Welfare regulations, for publication as a proposed rule at a later date. In the interim, we are removing the references to "accreditation" from Parts 1 and 2, as revised.

The proposed definition generated numerous comments expressing concern that otherwise qualified veterinarians would not satisfy the terms of the definition and would not be eligible to serve as attending veterinarians. We received 114 comments from the research community stating that under the proposed definition there would be an inadequate number of qualified or trained veterinarians to satisfy the demand for them. Five commenters expressed particular concern that otherwise qualified veterinarians might not be eligible to be attending veterinarians because they are graduates of foreign schools and do not have a certificate issued by the American Veterinary Medical Association's (AVMA) Education Commission for Foreign Veterinary Graduates. The definition as originally proposed would exclude graduates of European programs who can be licensed to practice in some states which do not require certification by the AVMA Education Commission for Foreign

Veterinary Graduates. These veterinarians would not be allowed to serve as attending veterinarians even within the state of licensure under the terms of the definition.

It was never our intent to disqualify otherwise qualified foreign educated veterinarians. We are revising the definition to include those veterinarians who are determined by the Administrator to have equivalent formal education. We believe that there will be an adequate supply of veterinarians satisfying the revised definition of "attending veterinarian."

Similarly, the definition of "licensed veterinarian" is changed to include those who graduated from an accredited school of veterinary medicine or who have received equivalent formal education, as determined by the Administrator, and are licensed to practice veterinary medicine in some state.

The initially proposed definition of "attending veterinarian" would require training and/or experience in the care and management of the species being attended. We received 407 comments (378 from the research community, 3 from exhibitors, and 26 from members of the general public) stating that this requirement is vague. Five dealers commented that veterinarians should not be required to have experience with the particular species being attended. We disagree since the variation among the different species of animals requires that the attending veterinarian be familiar with the different requirements to promote the animals' welfare. We also believe the terms "care and management" are commonly understood and applied in animal husbandry and are adequate to provide guidance to attending veterinarians. Accordingly, we are retaining this requirement in the revised definition.

Four commenters stated their concern that the proposed definition of "attending veterinarian" would improperly shift responsibility from the Institutional Animal Care and Use Committee (Committee) to the "Attending Veterinarian." Three commenters from the research community stated that we should substitute the word "authority" for "responsibility" in the definition.

The Committee, or IACUC, has defined areas of responsibility and authority under the Act and the regulations, and the definition of "attending veterinarian" does not shift this burden. However, to make this clear, we are incorporating the suggested wording change to alleviate any concern that the "attending veterinarian" would have responsibilities which properly belong to the Committee. Moreover, the facility, in accordance with Part 2 of the regulations, as revised, is responsible for activities involving animals and for establishing and maintaining the Committee.

The definition of "attending veterinarian" would be as follows:

> a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the Administrator; has received training and/or experience in the care and management of the species being attended; and who has direct or delegated authority for activities involving animals at a registered or licensed facility.

Business hours

We received a number of comments regarding the proposed definition of "business hours" as meaning "the hours between 7 a.m. and 7 p.m., Monday through Friday, except for statutory Federal holidays, each week of the year." We received 449 comments (424 from the research community and 25 from members of the general public) stating that the proposed hours are not the normal business hours for licensees and research facilities. We received 394 comments (332 from the research community, 22 from dealers, 9 from exhibitors, and 31 from members of the general public) stating that business hours should de defined as the normal business hours of the regulated entity, and 51 commenters (18 dealers and 33 from the research community) stated that business hours should be an 8-hour period between 7 a.m. and 7 p.m. We agree that some clarification of the definition is necessary to make clear our intent that for some reasonable time during the hours from 7 a.m. to 7 p.m. daily, every facility must make its animal housing facility(ies), animal use areas, and records available for APHIS inspection without an appointment or scheduled inspection being required. The facility would not have to be open during all hours between 7 a.m. and 7 p.m., and could be open fewer than 8 hours. For example, if a facility is open from noon until 7 p.m., it must be available for inspection at all times during those hours.

Accordingly, the definition of "business hours" is revised to be "a reasonable number of hours between 7 a.m. and 7 p.m., Monday through Friday, except for statutory Federal holidays, each week of the year, during which inspections by APHIS may be made."

Under this revised definition, facilities must be available for APHIS inspection every Monday through Friday, and not just on the days they are open for business or trade, since some facilities may be part-time operations or seasonal businesses but maintain animals year-round. The proposed range of hours would help avoid problems we have encountered in the past with some facilities which seem never to be open when APHIS inspectors arrive, or which purport to be open only at "other" times.

Commerce

Two commenters from the research community stated that the proposed definition of "commerce" should be clarified. We do not believe that the definition is unclear. We believe that the changes made to the current definition to indicate that intrastate activities are considered to be in commerce for purposes of the Act, and the inclusion of trade, traffic, transportation, or other commerce with any foreign country, will aid understanding of the term. The definition of "commerce" remains as proposed.

Committee

We received a number of comments concerning the proposed definition of "Committee." We received 311 comments (286 from the research community and 25 from members of the general public) stating that the Institutional Animal Care and Use Committee should be given the name used in the Act, that is, the Institutional Animal Committee, and 308 commenters (283 from the research community and 25 members of the general public) stated that research facilities should be given flexibility to identify the Committee by whatever name it selects. We received 121 comments from the research community stating that there is no statutory authority for requiring establishment of a Committee. This contention is incorrect. Section 13(b) of the Act authorizes the Secretary to require that each research facility establish at least one Institutional Animal Committee composed of members with sufficient ability "to assess animal care, treatment, and practices in experimental research * * *" (7 U.S.C. 2143(b)). We proposed the name "Institutional Animal Care and Use Committee" because it is descriptive of the areas of concern to the Committee, while the name "Institutional Animal Committee" is general and could lead to concern that the Committee would be involved in areas beyond the scope of the regulations. Our concern is not with the

name assigned to the Committee by a facility, but that the Committee, regardless of its name, carry out its responsibilities and duties. We proposed this name for purposes of uniformity and ease of reference. The definition of "Committee," including the name "Institutional Animal Care and Use Committee", remains as originally proposed.

Endangered species

We received one comment from the research community stating that the proposed definition of "endangered species" should be more specific than "those species defined in the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and as it may be subsequently amended." Another comment from the research community stated that the definition should read any "endangered or threatened species as listed under the Endangered Species Act of 1973 as amended." The Endangered Species Act includes species which are determined to be endangered or threatened because of certain factors set forth in the statute. Accordingly, our proposed definition encompasses the definition suggested by the latter commenter. We believe it is impractical to be more specific in the definition of "endangered species," since the list of species covered by the Endangered Species Act is a changing one, with additions and deletions.

Euthanasia

We received 324 comments (299 from the research community and 25 from members of the general public) stating that the definition of "euthanasia" should not refer to "immediate" death and that unconsciousness need only be rapid and not "instantaneous." As stated in the Supplementary Information accompanying the March 31, 1987 proposed rule, we believe our proposal describes humane destruction of an animal. Deletion of the requirement that death be "immediate" and requiring instead that unconsciousness need only be rapid instead of instantaneous could result in use of less humane methods of euthanasia which in turn could result in prolonged suffering by the animals. No changes have been made in the definition.

The Supplementary Information accompanying the definition of "euthanasia" stated that the method used should be consistent with the recommendations of the AVMA's current Panel on Euthanasia. Eight commenters from the research community stated that the definition of "euthanasia" should set forth the specific AVMA recommendations on methods of euthanasia. We received 317 comments (292 from the research community and 25 from members of the general public) stating that all reference to the AVMA Panel on Euthanasia recommendations should be removed from the proposal since the AVMA Panel is an independent body, not subject to APHIS direction. We disagree with these comments for the following reasons. The definition as originally proposed would allow use of any humane method for euthanizing animals and does not refer to the AVMA Panel on Euthanasia recommendations. We believe it is appropriate to allow facilities to determine which humane method they wish to use. If there is a question as to whether a certain method would be considered humane, we will issue a written opinion, upon request. We believe that the recommendations of the AVMA's current Panel on Euthanasia would meet the requirements of the proposed definition. For that reason, we referred to the recommendations in the Supplementary Information to provide further guidelines to facilities in determining what methods will be considered humane. This reference is not part of the regulations.

Exotic animal

We received 358 comments (333 from the research community and 25 from members of the general public) stating that the definition of "exotic animal" as proposed would include nonhuman primates, hamsters, and some other rodents, and that these species should be excluded from this term. Five commenters (2 from the research community, 1 exhibitor, 1 dealer, and 1 member of the general public) stated that the proposed definition is confusing in general.

The proposal defined "exotic animal" as:

> any animal not identified in the definition of "animal" provided in this Part that is native to a foreign country or of foreign origin or character, is not native to the United States, or was introduced from abroad. This term specifically includes animals such as, but not limited to, lions, tigers, leopards, elephants, camels, llamas, antelope, anteaters, kangaroos, and water buffalo. Species of foreign domestic cattle, such as, Ankole, Gayal, Yak are included in this group.

We agree that there could be some confusion as a result of the definition, since many animals commonly found in the United States or generally not considered exotic are "not native to the United States, or were introduced from abroad." In fact many species of dogs are not native to the United States. Therefore, we are clarifying the definition to exclude those animals specifically included in the definition of "animal." We are also removing llamas from the definition of "exotic animal" in this revised rule because of the increasing numbers of llamas used on farms for breeding purposes.

Farm animal

We received 319 comments (294 from the research community and 25 from members of the general public) stating that the proposed definition of "farm animal" is confusing since it defines farm animals in terms of their use rather than their species. Seven commenters stated that our definition should be consistent with the definition of "animal" as set forth in the Animal Welfare Act. The Act excludes the following animals from the definition of "animal":

> horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for improving animal nutrition, breeding, management or production efficiency, or for improving the quality of food or fiber.

The proposed definition is consistent with the definition of "animal" provided in the Act, in that it is the use or intended use which excludes farm animals from the Act, not their species. We are expanding the definition to include all the uses listed in the Act, in accordance with the commenters' suggestion, to avoid confusion.

Four commenters stated that the definition should refer to "warmblooded" domestic species to be consistent with the definition of "animal." We believe that this is unnecessary since "animal," as defined in the regulations, is limited to warmblooded species and there is no need to further identify farm animals as warmblooded.

As stated above, we are including llamas in the definition of farm animals when used or intended for use as farm animals, as set forth in the Act.

Housing facility

We received 60 comments from the research community objecting to the proposed definition of "housing facility" as "any land, premises, shed, barn building, trailer, or other structure or area housing or intended to house animals." These commenters stated that "housing facility" should be renamed "animal facility" and that these facilities should be distinguished from "animal study area," "acute research study area," "chronic research study area," and "holding facility." We have

considered those comments but do not agree with them. We believe there is no reason to distinguish animal study area, acute research study areas, chronic research study areas, and holding facilities for purposes of the standards, since these areas are all included within housing facilities and are subject to inspection and compliance with the regulations regardless of their name or research purpose. Also, the term "housing facility" applies to any facility used by any person subject to the Act to house animals, and is not limited to research facilities. The regulations pertaining to housing facilities contained in Part 2—"Regulations" and the proposed rule for Part 3—"Standards", published elsewhere in this issue of the Federal Register (see companion docket nos. 88–014 and 87–004, respectively), are equally applicable to all persons subject to the Act and to all parts of housing facilities. The definition remains as originally proposed.

Hybrid cross

Fourteen commenters from the research community objected to the proposed differentiation between domestic and wild hybrid cross animals and stated that all hybrids should be considered wild animals. The general consensus within the Agency remains that hybrid cross animals should be considered to be domesticated animals. For this reason and for the reasons provided in the Supplementary Information accompanying the March 31, 1987 proposed rule, the definition of "hybrid cross" remains as initially proposed.

Impervious surface

The proposed definition of "impervious surface" includes the requirement that "[f]luids on such surfaces will bead or run off, * * *". We received 363 comments (338 from research community and 25 from members of the general public) objecting to this portion of the definition because some nonpermeable floor surfaces will not cause fluids to bead up or fun off, but otherwise do meet the definition of "impervious surface." We agree that this can be the case with some impervious surfaces and are modifying this provision in the definition. Our concern is that the surfaces be those that can be readily cleaned and that they not absorb material which could contaminate the surface and cause problems with sanitization. The definition, as revised, includes surfaces on which fluid beads up and runs off and surfaces from which fluids can be removed without their being absorbed into the surface material.

Two dealers and two commenters from the research community stated that some species do not require impervious surfaces and that for some species impervious surfaces may in fact be detrimental to their well-being. We agree, and have addressed these situations in the standards provided in the proposed rule for Part 3—"Standards", published elsewhere in this issue of the Federal Register in companion docket no. 87–004. Those proposed standards require impervious surfaces in defined instances.

We received 317 comments (292 from the research community and 25 from members of the general public) stating that the requirements that impervious surfaces not retain odors is inappropriate since odors are a function of cleaning and not the surface. We disagree, since some surfaces absorb disturbing odors regardless of how well they are cleaned. This requirement remains in the definition.

Indoor housing facility

We received 352 comments (326 from the research community, 25 from members of the general public, and 1 from an exhibitor) stating that the requirement that an "indoor housing facility" must be capable of maintaining humidity levels of 30 to 70 percent is too rigid and should be deleted from the definition. We disagree, and we believe the required range of a 30 to 70 percent humidity level is a reasonable one. Most species of animals that would be housed in indoor housing facilities require humidity levels within this range for their general health and welfare. This is reflected in the standards provided in the proposed rule for Part 3—"Standards" and published elsewhere in this issue of the Federal Register in companion docket no. 87–004. We do not believe compliance with this requirement will prove burdensome. Facilities receiving NIH funds for research currently must provide assurance that they are in compliance with the requirements contained in the NIH Guide for the Care and Use of Laboratory Animals. The Guide provides humidity levels within this same range for dogs, cats, and nonhuman primates. The Guide provides a range of 40 to 70 percent for most other warmblooded animals. Moreover, since 1967, indoor housing facilities have been required under our regulations to have the capability of controlling the environment within the facility. The definition remains as originally proposed.

Inspector

In the March 31, 1987 proposal, we proposed to define the term, "Veterinary Services representative," as "any inspector or other person employed by the Department who is responsible for the performance of a function under the Act." (In accordance with a change in internal policy, the term, "Veterinary Services representative," has been replaced with "APHIS official" in the revised rule.) The term "inspector" also appears in Part 2 and 3 of the regulations (see companion docket nos. 88–014 and 87–004, respectively) but was not separately defined in the March 31, 1987 proposal. We believe it would be helpful to the public to define the term "inspector." Because an inspector is an APHIS official, the definition of each term would be the same. Accordingly, the term "inspector" is defined to mean "any person employed by the Department who is authorized to perform a function under the Act and the regulations in 9 CFR Parts 1, 2, and 3."

Major operative experiment

We received 74 comments, all from the research community, stating that the definition of "major operative experiment" should be changed from "any surgical intervention that penetrates and exposes a body cavity or that has the potential for producing a permanent disability" to any surgical intervention that both penetrates and exposes a major body cavity and/or is intended to cause physical or physiological impairment. We disagree.

It is necessary to define this term since the 1985 amendments to the Act plainly require standards providing that no animal be used in more than one major operative experiment from which it is allowed to recover, except (1) in cases of scientific necessity, (2) in cases of special circumstances as determined by the Secretary, or (3) when otherwise required by a research protocol (7 U.S.C. 2143(a)(3) (D) and (E)). There is no basis under the Act for requiring that a procedure result in an actual impairment or that it be performed with the established intent of causing physical or physiological impairment for it to be termed a "major operative experiment." The intended effect in performing a procedure cannot be relied upon to determine whether a procedure should be termed "major" or "minor" since that effect may or may not be accomplished. We consider that the potential for disability is sufficient to warrant considering the procedure to be "major." We do not regulate the intent underlying

experimentation, and intent should not enter into a definition of what is considered to be a "major operative experiment." The definition remains as originally proposed.

Mobile or traveling housing facility

Our proposal, published elsewhere in this issue of the **Federal Register** (see companion docket no. 87–004), to revise Part 3, Subparts A and D, would allow dogs, cats, and nonhuman primates to be maintained in four different types of animal housing facilities: indoor, outdoor, sheltered, and mobile or traveling housing facilities. Definitions for indoor, outdoor, and sheltered animal housing facilities were included in our March 31, 1987 proposal to revise Part 1 (see 52 FR 10292–10298). However, no definition of the term "mobile or traveling housing facility" was proposed. Therefore, we are adding a definition of the term as follows:

> a transporting vehicle, such as a truck, trailer, or railway car, used to house animals while traveling for exhibition or public education purposes.

These purposes would include circuses, carnivals, traveling zoos, education exhibits, and traveling animal acts.

Non-conditioned animals

One exhibitor commented that the proposed definition of "non-conditioned animal" is vague. The current definition is "animals which have not been subjected to special care and treatment for sufficient time to stabilize and, where necessary, to improve their health to make them more suitable for research purposes." Since 1967 the definition of this term has been substantially as we proposed, except that the definition referred only to animals intended for use in research facilities. The proposed definition deletes the phrase "to make them more suitable for research purposes," making the term applicable to animals used by all persons subject to the Act and the regulations. We believe this change is necessary since it is equally applicable to animals held by dealers and exhibitors and to animals in transport. We inadvertently did not explain this change in the Supplementary Information to the proposed rule. The definition remains as proposed in the March 31, 1987 proposal.

Outdoor housing facility

The current definition of "outdoor housing facility" is "any structure or building, housing or intended to house animals, which does not meet the definition of "indoor housing facility"." In the March 31, 1987 proposal and in this rule, we added a definition for another type of housing facility, known as a "sheltered housing facility." Accordingly, we proposed to define the term "outdoor housing facility" as a structure, land, or premise, housing or intended to house animals, which does not meet the definition of an indoor housing facility or a sheltered housing facility and in which temperatures cannot be controlled within set limits." Revising the definition became necessary because a sheltered housing facility is neither an outdoor nor an indoor housing facility. In this document, we are also adding a definition of the term, "mobile or traveling housing facility," which is another type of housing facility that may be used to house animals under the regulations. (Proposed specifications pertaining to sheltered and mobile or traveling animal housing facilities when used to house dogs, cats, and nonhuman primates appear in the proposed rule for Part 3—"Standards," companion docket no. 87–004, published elsewhere in this issue of the **Federal Register.** To avoid having to amend the definition of "outdoor housing facility" each time another type of housing facility is authorized for use under the regulations, we are revising the definition in this rule to mean "a structure, land, or premise, housing or intended to house animals, which does not meet the definition of any other type of housing facility provided in the regulations and in which temperatures cannot be controlled within set limits."

Three commenters (2 from the research community and 1 exhibitor) stated that a more stringent definition of "outdoor housing facility" is necessary. We believe that this is unnecessary and could prove to be too limiting in application. We encourage the design and development of animal facilities which provide animals with natural environments appropriate for the species of animal housed and which allow ready access to runs and similar areas for exercise and social interaction. We believe that providing a more exacting definition could discourage the construction of animal housing facilities of this type.

Painful procedure

We received 345 comments (320 from the research community and 25 from members of the general public) stating that the definition of "painful procedure" should be revised to be consistent with the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" which appears in the U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals ("PHS Policy"). All PHS-conducted or supported activities involving animals must comply with the PHS Policy. Principle V provides that "[p]rocedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anethesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents." We used similar language in the proposed definition of "painful procedure" and, as provided in Principle IV, we proposed using human beings as the reference point for determining whether a procedure is a "painful procedure." Principle IV states that "[u]nless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals." We believe that our proposed definition is consistent with the PHS Policy and with the advice of the commenters, and that no revision is necessary. We received 142 comments from the research community stating that this approach is too anthropomorphic. We believe that using human standards of pain is necessary to properly define when a procedure is to be considered painful and to make the definition meaningful to those persons applying it. The definition remains as originally proposed.

Paralytic drug

In accordance with section 13(a)(3)(C)(iv) of the Act, (7 U.S.C. 2143(a)(3)(C)(iv)), § 2.30(e)(9) of the revised rule for Part 2 (see companion docket no. 88–014) provides that each research facility that engages in a painful practice or procedure using an animal must prohibit the use of paralytic drugs without anesthesia. Section 2.30(e)(10), as revised, would require that the research facility establish a written policy to ensure compliance with the prohibition. These provisions were originally proposed in § 2.30(e)(4) at 52 FR 10312.

We received 31 comments from the research community in response to the proposed rule stating that the term "paralytic drug" should be defined. We agree and are adding a definition of the term as follows:

> a drug which causes partial or complete loss of muscle contraction and which has no anesthetic or analgesic properties, so that the animal cannot move, but is completely aware of its surroundings and can feel pain.

This definition is in accordance with the generally accepted usage of the term among professionals and professional

organizations and is consistent with the intent of the Act.

Pet animal

We received 5 comments (4 from the research community and 1 from a dealer) stating that the definition of "pet animal" should exclude exotic or wild animals. We agree and intended to exclude them by using the phrase "any animal that has commonly been kept as a pet animal" in the definition. To clarify this point further we are adding examples of common household pets to the definition, such as dogs, cats, guinea pigs, rabbits, and hamsters.

Positive physical contact

Our proposal to amend Part 3, Subpart A (see companion docket no. 87–004), would require that individually housed dogs receive positive physical contact with humans. We are adding a definition of the term "positive physical contact" as it is commonly understood by the public, that is, "petting, stroking, or other touching, which is beneficial to the well-being of the animal."

Primary enclosure

We did not receive any comments addressing the proposed definition of "primary enclosure." We are replacing the word "chain" in the rule with "tether," however, to include all like devices used to restrict an animal's radius of movement.

Principal investigator (investigator)

The revised rule for Part 2 of the regulations (see companion docket no. 88–014) would require that research facilities impose certain duties and responsibilities on the principal investigator in planning and carrying out the animal care and use procedure (ACUP) of a research project. We are adding a definition of the term "principal investigator" as "an employee of a research facility responsible for a proposal to conduct research and for the design and implementation of research involving animals." This is the meaning of the term as it is used in the research community. It is also the meaning of the term as it is used by the U.S. Public Health Service in its "Public Health Service Policy on Humane Care and Use of Laboratory Animals." The Policy provides guidelines, issued by the U.S. Public Health Service under the Health Research Extention Act of 1985, for the proper care and treatment of animals used in biomedical and behavioral research. We are adding the definition to Part 1 of the regulations so that members of the general public will share the same understanding of the term.

Protocol

We proposed to define the term "Protocol" as "an investigator's plan for the use of animals in a study of a biomedical problem." We received 409 comments (384 from the research community and 25 from members of the general public) objecting to use of the term "protocol" and to our proposal to require review and approval of protocols by a facility's Institutional Animal Care and Use Committee. We received 342 comments (317 from the research community and 25 from members of the general public) stating that the term is not defined in the Animal Welfare Act and should be deleted from the regulations altogether.

Although the term is not defined in the Act it does appear in section 13 of the Act (7 U.S.C. 2143), which mandates the imposition of certain responsibilities upon research facilities and upon their Committee for carrying out the purposes of the Act. We believe that use of the term "protocol" is therefore proper. We understand from the comments we received that use of this term may imply to some research facilities that APHIS would be involved in the evaluation of the design, outlines, guidelines, and scientific merit of proposed research. That is not our intent. Our concern is with the animal care and use portion of the research, that is, how the research will treat or affect an animal, the condition of an animal, and the circumstances under which an animal is maintained. Accordingly, to clarify our intentions and avoid any misunderstanding, the term "protocol" is changed in this revised rule to "animal care and use procedure" ("ACUP"). The definition is also clarified to include an investigator's plan for the care of animals in addition to a plan for the use of animals.

The comments we received concerning our statutory authority to require review of what is now termed the "animal care and use procedure" are addressed in companion docket number 88–014, Part 2—"Regulations," published elsewhere in this issue of the **Federal Register**.

Research facility

Thirty-seven commenters from the research community stated that the word "biomedical" should not appear in the definition of "research facility." In writing our proposed definition of "research facility," we tried to follow the language of the Act as closely as possible. This term appears in the Act's definition of "research facility" (7 U.S.C. 2132(e)).

Nineteen commenters from the research community stated that the definition of "research facility" should exclude government agencies responsible for protection and management of the wildlife resources of a state. Again, in writing our proposed definition of "research facility," we tried to follow the language of the Act as closely as possible, and the Act allows no specific exclusion of government agencies of the type described by the commenters.

After carefully considering these comments, we have decided to adopt the Act's definition of "research facility" and use it in our regulations. We believe this would avoid confusion and ensure that our regulations accomplish the intent of the Act. The only change we are making in the definition is to replace the term "Secretary" with the term "Administrator."

Retail pet store

In our proposed definition of "retail pet store," reference to exhibiting nonpet animals was inadvertently omitted, although it was included in the Supplementary Information. We are revising the definition of "retail pet store" from that appearing in the March 31, 1987 proposal to exclude establishments or persons exhibiting or offering to exhibit any wild or exotic or other nonpet species of warmblooded animals (except birds), such as skunks, raccoons, nonhuman primates, squirrels, ocelots, foxes, coyotes, etc., in addition to those selling or offering to sell these nonpet species. These establishments and persons would be required to obtain a license under Part 2 of the regulations.

We are also adding a fifth exclusion for retail pet stores that exhibit animals in a room that is separate from or adjacent to a retail pet store, in an outside area, or anywhere off the pet store premises. If the pet animals are taken off the premises for purposes of exhibition, such as at schools, parades, or shopping malls, or are placed in outside areas or areas adjacent to the pet store for use in a petting zoo-type exhibit, the establishment or person exhibiting the pet animals must obtain a license under Part 2 of the regulations. This exclusion would prevent exhibitors from claiming to be retail pet stores in order to avoid being licensed in accordance with Part 2 of the regulations.

We are deleting mink from the list of pet animals sold by retail pet stores in response to a comment regarding the proposed definition of "wild animal." We are doing so because of their vicious nature. Mink are not regulated animals,

however, when used or intended for use solely for food or fiber purposes.

Sanitize

We received 4 comments from the research community stating that "sanitize" should be redefined so as to require removal of dirt, debris and harmful contamination, instead of requiring removal and destruction, to the maximum degree that is practical, of any agents injurious to health. The definition of "sanitize" has been the same as we proposed since 1966. We do not believe it appropriate to delete the requirement to destroy injurious agents since elimination of these agents results in a more healthful environment for animals that may be exposed to them. The definition remains as proposed.

Sheltered housing facility

Three commenters from the general public stated that the definition of "sheltered housing facility" should be deleted as this type of facility could lead to mistreatment of the housed animals. In the proposed rule for Part 3—"Standards" (see companion docket no. 87–004 published elsewhere in this issue of the **Federal Register**), we have proposed specifications for this type of housing facility which include requirements for heating, cooling, ventilation, cleaning, drainage, and lighting. We believe that a sheltered housing facility which is in compliance with these proposed standards can be effectively used to house animals in a humane manner in accordance with the Act.

Wild animal

We proposed to define "wild animal" as:

> any animal which is now or historically has been found in the wild, or in the wild state, within the boundaries of the United States, its territories, or possessions. This term includes, but is not limited to animals such as: Buffalo, deer, skunk, opossum, raccoon, armadillo, coyote, squirrel, fox, wolf.

One dealer and one member of the general public commented in disagreement with our proposed definition. One dealer stated that ferrets and mink should be classified as wild animals, and 9 dealers and 2 exhibitors stated that deer, llama, and buffalo should be classified as domestic animals. As explained above under "Retail pet store," we agree that mink should be considered a "wild animal" due to its vicious nature. The definition of "wild animal" will be changed to include mink. We disagree with the comment with regard to ferrets, however, since they are considered to be easily handled and relatively nondangerous, and are now commonly bred and kept as pet animals. We also disagree with classifying deer as domestic animals. Although some individuals may be raised in captivity and would be considered tame, most deer are found in the wild. However, we do agree with the commenters with regard to buffalo. Buffalo are nearly extinct in the wild. Most now exist in game preserves, where they are displayed in natural settings. Under these circumstances they are not wild animals. Therefore, we are removing them from the definition of "wild animal." We are making no change in the definition of "wild animal" with regard to llamas because llamas were not include as wild animals in our proposed definition of the term. We also want to make it clear that wild rats and mice are included in the definition of wild animal, as distinguished from rats and mice bred in captivity for use in research, and that wild rats and mice are regulated animals under the Act.

We received no comments concerning the remaining definitions and they remain in this rule as originally proposed.

Miscellaneous

As a result of a change in internal policy, the term "Veterinary Services" is replaced with "APHIS" wherever it appears and the definition of "Veterinary Services" is not included in this revised rule. We have defined "APHIS" to mean "the Animal and Plant Health Inspection Service, United States Department of Agriculture."

In order to be consistent with this change in policy, the term "Veterinary Services representative," is replaced with "APHIS official." We proposed to define the term, "Veterinary Services representative" to mean "any inspector or other person employed by the Department who is responsible for the performance of a function under the Act." We have added a definition of the term "inspector" in this revised rule, as explained above. For this reason, the definition of "APHIS official" does not specifically refer to inspectors. We are using the word "authorized" in place of "responsible" in the definition of "APHIS official" because the Secretary of Agriculture is responsible for performance under the Act. Department employees are authorized to perform certain functions. We are also clarifying the definition by including the performance of functions under the regulations as well as under the Act, because the regulations are promulgated under the Act. Accordingly, "APHIS official" is defined to mean "any person employed by the Department who is authorized to perform a function under the Act and the regulations in 9 CFR Parts 1, 2, and 3."

We are correcting the following typographical errors which appeared in the March 31, 1987 proposal:

(1) We are correcting two errors in the proposed definition of "Class "B" licensee (dealer)". In the first sentence the reference to "§ 1.1(q)" has been changed to "§ 1.1" since we are not lettering the paragraphs, and in the second sentence "at an auction sale" has been corrected to read "of an auction sale."

(2) We are similarly changing the reference to "§ 1.1(x)" in the definition of "Class "C" licensee (exhibitor)" to "§ 1.1" since we are not lettering the paragraphs.

(3) In the definition of "endangered species," the closing parentheses are placed after the statutory citation instead of the period.

Statutory authority for this Proposed Rule

This proposed rule is issued pursuant to the Animal Welfare Act (Act), as amended, 7 U.S.C. 2131–2157. Congress recently added significantly to the Secretary's responsibilities under the Act by amendments in the Food Security Act of 1985, Pub. L. No. 99–198, approved December 23, 1985. The declared policy of the Act is to ensure that animals intended for use in research facilities, as pets, or for exhibition purposes are provided humane care and treatment; to assure the humane treatment of animals during transportation; and to prevent the sale of stolen animals.

The Act mandates that the Secretary of Agriculture promulgate regulations and standards to govern the humane handling, care, treatment, and transportation of animals by dealers, exhibitors, research facilities, carriers, and intermediate handlers. To accomplish this, the Secretary must define certain key words used in the regulations and standards so that persons subject to the Act, regulations, and standards can comply with their requirements.

The Act itself defines some of the terms which appear in this rule. The Act also authorizes the Secretary to promulgate such rules, including additional definitions, as he deems necessary to effectuate the purposes of the Act.

Executive Order 12291

On March 31, 1987, the Department published proposed rules to amend Part 1—"Definition of Terms" and Part 2—"Regulations," of the Animal Welfare regulations (52 FR 10292, 10298) in order to implement the 1985 amendments to the Animal Welfare Act, Pub. L. 99–198, the "Food Security Act." The proposed action was reviewed pursuant to Executive Order 12291 and it was determined that it did not constitute a "major rule." We solicited comments with regard to the proposed rules, and have made modifications to those rules as explained in the "Supplementary Information." At this time, we are also publishing a proposal to revise the standards contained in 9 CFR Part 3—"Standards," published elsewhere in this issue of the Federal Register.

In revising Parts 1 and 2, and in preparing the proposed rule for Part 3, we assessed the economic effects of the regulations in accordance with the requirements of Executive Order 12291. We considered alternative approaches to carrying out our statutory mandate, many of which we adopted. A regulatory impact analysis of revised Parts 1 and 2, and the proposal for Part 3 was prepared. Based on that analysis, which included consideration of both quantifiable and nonquantifiable effects of the rules, the Administrator has determined that Parts 1 and 2 would have an impact on the economy in excess of $100 million annually, and would constitute a "major rule."

The following requirements under Parts 1 and 2 represent some of the major costs to the regulated industries: (1) The establishment and responsibilities of the animal care and use committees; (2) aseptic surgical facilities and adequate pre- and post-procedural care; (3) increased responsibilities for attending veterinarians; (4) additional administrative responsibilities; (5) increases in license fees; and (6) identification for dogs and cats less than 16 weeks of age.

The economic impacts of these rules are discussed in more detail in a regulatory impact analysis, which is available for public inspection in Room 1141 of the South Building, U.S. Department of Agriculture between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays (address above). Main findings of this analysis are summarized below.

SUMMARY OF REGULATORY IMPACT ANALYSIS

Costs	Benefits
Direct	Direct
Regulated industry.....	Increased public satisfaction from improved animal welfare*.
Capital expenditure:	
(all parts) $876 million.....	Improved research information*.
(parts 1–2) $142 million	Productivity gains for regulated industries*.
Annual costs:	
(all parts) $207 million.....	
(parts 1–2) $126 million	
APHIS program costs impact on federal sites* $2 million.	
Indirect	Indirect
Opportunity costs for users of biomedical research (goods and service), pet industry, and animal exhibits*.	Market effects for suppliers of animal husbandry products*.
Increased federal financial support for biomedical community*.	Non-market effects*.
Non-market effects*.	

* Not quantified.

Compliance with more stringent federal regulations on the humane care and treatment of animals used for research, testing, teaching, exhibition, and business ventures would result in major direct and indirect effects imposed on the regulated industries and the general economy. An examination of the estimated cost impacts indicates that the amended regulations constitute a "major rule" based on annual effects in excess of $100 million on the economy and large cost increases on regulated industries for animal uses and maintenance, in particular to the biomedical research community. However, this study could not properly assess the relative significance of these cost increases on the regulated industry or the presence of adverse effects on competition, innovation, and the ability of domestic enterprises to compete with foreign enterprises in international markets.

Regulated persons or establishments will be required to spend approximately $876 million in capital expenditures over the next two or three years. Of this amount approximately 16 percent is attributable to Parts 1 and 2. If Parts 1 and 2 were enforced separately, regulated research facilities will be required to spend approximately $142 million to renovate, equip, replace, or construct aseptic surgical facilities, and provide for adequate per- and post-surgical care. Capital expenditures attributable to Part 3 include costs for renovation, equipment replacement, and new construction of animal housing facility space. Capital expenditures to improve animal housing facilities would result from the new minimum standards for general environmental conditions, space or primary enclosure size requirements, exercise of dogs, and enrichment of nonhuman primate enclosures.

In addition to capital expenditures, total annual operating exenditures estimated at $207 million will also be required. Approximately 60 percent of this total ($126 million) is accounted for by Parts 1 and 2, primarily the requirements for the establishment and operations of the institutional animal care and use committees, additional responsibilities for attending veterinarians, and record-keeping requirements. Annual expenditures attributable to Part 3 would result from the need for additional personnel (animal handlers) to execise dogs, and the daily maintenance of animal housing facilities.

An important result of this regulatory analysis is that policy decisions must consider other direct and indirect effects associated with the promulgation and enforcement of federal rules. Increased federal legislation causes important economic benefits and costs which are unevenly distributed among registrants and licensees. Direct benefits accrue to society by knowing that animals may be better cared for and treated humanely. The value of these social benefits are subject to personal preferences and concerns. Improvements in the well-being of regulated animals may also provide gains in productivity to the industry. On the other hand, increased costs of compliance will be passed from the regulated industry to consumers who purchase their goods and services. For example, the field of biomedical research and education depends heavily on the use of animals to conduct tests and experiments. Increased costs for animal uses have broader economic and health implications for all of us. Study results do not suggest that these regulations would cause establishments to abandon the use of animals since current biomedical research outlays are in excess of $12.8 billion per year. Nonetheless, there could be important effects associated with allocating additional funds or expenditures to comply with the amended animal welfare regulations.

Regulatory Flexibility Act

As part of the regulatory impact analysis performed by the Department we have analyzed the potential impact on small entities of Parts 1 and 2, as revised, and the proposal to amend Part

3 of the Animal Welfare regulations, as required by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Based upon our analysis, we have determined that Parts 1 and 2 of the regulations would affect all regulated small entities, primarily by increases in annual license fees and identification requirements for dogs and cats. However, these economic impacts would not be significant. It is anticipated that the largest impact on small entities would result from Part 3—"Standards", if it is implemented as proposed. Under these circumstances the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with state and local officials. (See 7 CFR 3015, Subpart V.)

Paperwork Reduction Act

In accordance with section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. 3507), the information collection provisions that are included in this proposed rule will be submitted for approval to the Office of Management and Budget (OMB). Your written comments will be considered if you submit them to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. You should submit a duplicate copy of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 866, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

List of Subjects in 9 CFR Part 1

Animal welfare, Animal housing, Dealers, Exhibitors, Research facilities, Humane animal handling.

Accordingly, we are proposing to amend 9 CFR Part 1 as follows:

PART 1—DEFINITION OF TERMS

1. The authority citation for Part 1 would be revised to read as follows:

Authority: 7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2146, 2147, 2151; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 1.1 would be revised to read as follows:

§ 1.1 Definitions

For the purposes of this subchapter, unless the context otherwise requires, the following terms shall have the meanings assigned to them in this section. The singular form shall also signify the plural and the masculine form shall also signify the feminine. Words undefined in the following paragraphs shall have the meaning attributed to them in general usage as reflected by definitions in a standard dictionary.

"Act" means the Act of August 24, 1966 (Pub. L. 89–544), (commonly known as the Laboratory Animal Welfare Act), as amended by the Act of December 24, 1970 (Pub. L. 91–579), (the Animal Welfare Act of 1970), the Act of April 22, 1976 (Pub. L. 94–279), (the Animal Welfare Act of 1976), and the Act of December 23, 1985 (Pub. L. 99–198), (the Food Security Act of 1985), and as it may be subsequently amended.

"Administrative unit" means the organizational or management unit at the departmental level of a research facility.

"Administrator" means the Administrator of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or any other official of the Animal and Plant Health Inspection Service to whom authority has been delegated to act in his stead.

"Ambient temperature" means the air temperature surrounding the animal.

"Animal" means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warmblooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes: Birds, rats and mice bred for use in research, and horses and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.

"Animal act" means any performance of animals where such animals are trained to perform some behavior or action or are part of a show, performance, or exhibition.

"Animal care and use procedure" (ACUP) means an investigator's plan for the care and use of animals in a study of a biomedical problem.

"APHIS" means the Animal and Plant Health Inspection Service, United States Department of Agriculture.

"APHIS official" means any person employed by the Department who is authorized to perform a function under the Act and the regulations in 9 CFR Parts 1, 2, and 3.

"Area Veterinarian in Charge" means a veterinarian or his designee, employed by APHIS, who is assigned by the Administrator to supervise and perform the official work of APHIS in a given State or States. As used in Part 2 of this subchapter, the Area Veterinarian in Charge shall be deemed to be the person in charge of the official work of APHIS in the State in which the dealer, exhibitor, research facility, intermediate handler, carrier, or operator of an auction sale has his principal place of business.

"Attending veterinarian" means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the Administrator; has received training and/or experience in the care and management of the species being attended; and who has direct or delegated authority for activities involving animals at a facility subject to the jurisdiction of the Secretary.

"Business hours" means a reasonable number of hours between 7 a.m. and 7 p.m., Monday through Friday, except for legal Federal holidays, each week of the year, during which inspections by APHIS may be made.

"Business year" means the 12-month period during which business is conducted, and may be either on a calendar or fiscal-year basis.

"Carrier" means the operator of any airline, railroad, motor carrier, shipping line, or other enterprise which is engaged in the business of transporting any animals for hire.

"Cat" means any live or dead cat (Felis catus) or any cat-hybrid cross.

"Class "A" licensee" (breeder) means a person subject to the licensing requirements under Part 2 and meeting the definition of a "dealer" (§ 1.1), and whose business involving animals consists only of animals that are bred and raised on the premises in a closed or stable colony and those animals acquired for the sole purpose of maintaining or enhancing the breeding colony.

"Class "B" licensee" means a person subject to the licensing requirements under Part 2 and meeting the definition of a "dealer" (§ 1.1), and whose business includes the purchase and/or resale of any animal. This term includes brokers, and operators of an auction sale, as such individuals negotiate or arrange for the purchase, sale, or transport of

animals in commerce. Such individuals do not usually take actual physical possession or control of the animals, and do not usually hold animals in any facilities. A class "B" licensee may also exhibit animals as a minor part of the business.

"Class "C" licensee" (exhibitor) means a person subject to the licensing requirements under Part 2 and meeting the definition of an "exhibitor" (§ 1.1), and whose business involves the showing or displaying of animals to the public. A class "C" licensee may buy and sell animals as a minor part of the business in order to maintain or add to his animal collection.

"Commerce" means trade, traffic, transportation, or other commerce—

(1) Between a place in a State and any place outside of such State, including any foreign country, or between points within the same State but through any place outside thereof, or within any territory, possession, or the District of Columbia; or

(2) Which affects the commerce described in this part.

"Committee" means the Institutional Animal Care and Use Committee established under section 13(b) of the Act. It shall consist of at least three (3) members, one of whom is the attending veterinarian of the research facility and one of whom is not affiliated in any way with the facility other than as a member of the Committee. The research facility shall establish the Committee for the purpose of evaluating the care, treatment, housing, and use of animals, and for certifying compliance with the Act by the research facility.

"Dealer" means any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of: Any dog or other animal whether alive or dead (including unborn animals, organs, limbs, blood, serum, or other parts) for research, teaching, testing, experimentation, exhibition, or for use as a pet; or any dog for hunting, security, or breeding purposes. This term does not include: A retail pet store, as defined in this section, unless such store sells any animals to a research facility, an exhibitor, or a dealer (wholesale); or any person who does not sell, or negotiate the purchase or sale of any wild or exotic animal, dog, or cat and who derives no more than $500 gross income from the sale of animals other than wild or exotic animals, dogs, or cats, during any calendar year.

"Department" means the U.S. Department of Agriculture.

"Deputy Administrator" means the Deputy Administrator for Veterinary Services or any other official of Veterinary Services to whom authority has been delegated to act in his stead.

"Dog" means any live or dead dog (Canis familiaris) or any dog-hybrid cross.

"Dwarf hamster" means any species of hamster such as the Chinese and Armenian species whose adult body size is substantially less than that attained by the Syrian or Golden species of hamsters.

"Endangered species" means those species defined in the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and as it may be subsequently amended.

"Euthanasia" means the human destruction of an animal accomplished by a method which produces instantaneous unconsciousness and immediate death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent which causes painless loss of consciousness and subsequent death.

"Exhibitor" means any person (public or private) exhibiting any animals, which were purchased in commerce or the intended distribution of which affects commerce, or will affect commerce, to the public for compensation, as determined by the Secretary. This term includes carnivals, circuses, animal acts, zoos, and educational exhibits, exhibiting such animals whether operated for profit or not. This term excludes retail pet stores, horse and dog races, organizations sponsoring and all persons participating in State and county fairs, livestock shows, rodeos, field trials, coursing events, purebred dog and cat shows and any other fairs or exhibitions intended to advance agricultural arts and sciences as may be determined by the Secretary.

"Exotic Animal" means any animal not identified in the definition of "animal" provided in this part that is native to a foreign country or of foreign origin or character, is not native to the United States, or was introduced from abroad. This term specifically includes animals such as, but not limited to, lions, tigers, leopards, elephants, camels, antelope, anteaters, kangaroos, and water buffalo, and species of foreign domestic cattle, such as Ankole, Gayal, and Yak.

"Farm animal" means any domestic species of cattle, sheep, swine, goats, llamas, or horses, which are normally and have historically, been kept and raised on farms in the United States, and used or intended for use as food or fiber, or for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. This term also includes animals such as rabbits, mink, and chinchilla, when they are used solely for purposes of meat or fur, and animals such as horses and llamas when used solely as work and pack animals.

"Federal agency" means an Executive agency as such term is defined in section 105 of Title 5, United States Code, and with respect to any research facility means the agency from which the research facility receives a Federal award for the conduct of research, experimentation, or testing involving the use of animals.

"Federal award" means any mechanism (including a grant, award, loan, contract, or cooperative agreement) under which Federal funds are used to support the conduct of research, experimentation, or testing, involving the use of animals. The permit system established under the authorities of the Endangered Species Act, the Marine Mammal Protection Act, and the Migratory Bird Treaty Act, are not considered to be Federal awards under the Animal Welfare Act.

"Federal research facility" means such department, agency, or instrumentality of the United States which uses live animals for research or experimentation.

"Handling" means petting, feeding, watering, cleaning, manipulating, loading, crating, shifting, transferring, immobilizing, restraining, treating, training, working and moving, or any similar activity with respect to any animal.

"Housing facility" means any land, premises, shed, barn, building, trailer, or other structure or area housing or intended to house animals.

"Hybrid cross" means an animal resulting from the crossbreeding between two different species or types of animals. Crosses between wild animal species, such as lions and tigers, are considered to be wild animals. Crosses between wild animal species and domestic animals, such as dogs and wolves or buffalo and domestic cattle, are considered to be domestic animals.

"Impervious surface" means a surface that does not permit the absorption of fluids. Such surfaces are those that can be thoroughly and repeatedly cleaned and disinfected, will not retain odors, and from which fluids bead up and run off or can be removed without their being absorbed into the surface material.

"Indoor housing facility" means any structure or building with environmental controls housing or intended to house animals and meeting the following three requirements:

(1) It must be capable of controlling the temperature within the building or structure within the limits set forth for that species of animal, of maintaining humidity levels of 30 to 70 percent and of rapidly eliminating odors from within the building; and

(2) It must be an enclosure created by the continuous connection of a roof, floor, and walls (a shed or barn set on top of the ground does not have a continuous connection between the walls and the ground unless a foundation and floor are provided); and

(3) It must have at least one door for entry and exit that can be opened and closed (any windows or openings which provide natural light must be covered with a transparent material such as glass or hard plastic).

"Intermediate handler" means any person, including a department, agency, or instrumentality of the United States or of any State or local government (other than a dealer, research facility, exhibitor, any person excluded from the definition of a dealer, research facility, or exhibitor, an operator of an auction sale, or a carrier), who is engaged in any business in which he receives custody of animals in connection with their transportation in commerce.

"Inspector" means any person employed by the Department who is authorized to perform a function under the Act and the regulations in 9 CFR Parts 1, 2, and 3.

"Isolation" in regard to marine mammals means the physical separation of animals to prevent contact and a separate, noncommon, water circulation and filtration system for the isolated animals.

"Licensed veterinarian" means a person who has graduated from an accredited school of veterinary medicine or has received equivalent formal education as determined by the Administrator, and who has a valid license to practice veterinary medicine in some State.

"Licensee" means any person licensed according to the provisions of the Act and the regulations in Part 2 of this subchapter.

"Major operative experiment" means any surgical intervention that penetrates and exposes a body cavity or that has the potential for producing a permanent disability.

"Minimum horizontal dimension" (MHD) means the diameter of a circular pool of water, or in the case of a square, rectangle, oblong, or other shape pool, the diameter of the largest circle that can be inserted within the confines of such a pool of water.

"Mobile or traveling housing facility" means a transporting vehicle such as a truck, trailer, or railway car, used to house animals while traveling for exhibition or public education purposes.

"Nonconditioned animals" means animals which have not been subjected to special care and treatment for sufficient time to stabilize, and where necessary, to improve their health.

"Nonhuman primate" means any nonhuman member of the highest order of mammals including prosimians, monkeys, and apes.

"Operator of an auction sale" means any person who is engaged in operating an auction at which animals are purchased or sold in commerce.

"Outdoor housing facility" means any structure, building, land, or premise, housing or intended to house animals, which does not meet the definition of any other type of housing facility provided in the regulations and in which temperatures cannot be controlled within set limits.

"Painful procedure" as applied to any animal means any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or other minor procedures.

"Paralytic drug" means a drug which causes partial or complete loss of muscle contraction and which has no anesthetic or analgesic properties, so that the animal cannot move, but is completely aware of its surroundings and can feel pain.

"Person" means any individual, partnership, firm, joint stock company, corporation, association, trust, estate, or other legal entity.

"Pet animal" means any animal that has commonly been kept as a pet in family households in the United States, such as dogs, cats, guinea pigs, rabbits, and hamsters. This term excludes exotic animals and wild animals.

"Positive physical contact" means petting, stroking, or other touching which is beneficial to the well-being of the animal.

"Primary conveyance" means the main method of transportation used to convey an animal from origin to destination, such as motor vehicle, plane, ship, or train.

"Primary enclosure" means any structure or devide used to restrict an animal or animals to a limited amount of space, such as a room, pen, run, cage, compartment, pool, hutch, or tether. In the case of animals restrained by a tether (e.g., dogs on chains), it includes the shelter and the area within reach of the tether.

"Principal investigator" means an employee of a research facility responsible for a proposal to conduct research and for the design and implementation of research involving animals.

"Quorum" means a majority of the Committee members.

"Random source" means dogs and cats obtained from animal pounds or shelters, auction sales, or from any person who did not breed and raise them on his or her premises.

"Registrant" means any research facility, carrier, intermediate handler, or exhibitor not required to be licensed under section 3 of the Act, registered pursuant to the provisions of the Act and the regulations in Part 2 of this subchapter.

"Reseach facility" means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments: *Provided,* That the Administrator may exempt, by regulation, any such school, institution, organization, or person that does not use or intend to use live dogs or cats, except those schools, institutions, organizations, or persons, which use substantial numbers (as determined by the Administrator) of live animals the principal function of which schools, institutions, organizations, or persons, is biomedical research or testing, when in the judgment of the Administrator, any such exemption does not vitiate the purpose of the Act.

"Retail pet store" means any outlet where only the following animals are sold or offered for sale, at retail, for use as pets: Dogs, cats, rabbits, guinea pigs, hamsters, gerbils, rats, mice, gophers, chinchilla, domestic ferrets, domestic farm animals, birds, and coldblooded species. Such definition excludes—

(1) Establishments or persons who deal in dogs used for hunting, security, or breeding purposes;

(2) Establishments or persons exhibiting, selling, or offering to exhibit or sell any wild or exotic or other nonpet species or warmblooded animals (except birds), such as skunks, raccoons, nonhuman primates, squirrels, ocelots, foxes, coyotes, etc.;

(3) Any establishment or person selling warmblooded animals (except birds, and laboratory rats and mice) for research or exhibition purposes; and

(4) Any establishment wholesaling any animals (except birds, rats and mice).

(5) Any establishment exhibiting pet animals in a room that is separate from or adjacent to the retail pet store, or in an outside area, or anywhere off the retail pet store premises.

"Sanitize" means to make physically clean and to remove and destroy, to the maximum degree that is practical, agents injurious to health.

"Secretary" means the Secretary of Agriculture of the United States or his representative who shall be an employee of the Department.

"Sheltered housing facility" means a housing facility which provides the animals with shelter; protection from the elements; and protection from temperature extremes at all times. A sheltered housing facility may consist of runs or pens totally enclosed in a barn or building, or of connecting inside/outside runs or pens with the inside pens in a totally enclosed building.

"Standards" means the requirements with respect to the humane housing, exhibition, handling, care, treatment, temperature, and transportation of animals by dealers, exhibitors, research facilities, carriers, intermediate handlers, and operators of auction sales as set forth in Part 3 of this subchapter.

"State" means a State of the United States, the District of Columbia, Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or any other territory or possession of the United States.

"Transportation device" means an interim vehicle or device, other than man, used to transport an animal between the primary conveyance and the terminal facility or in and around the terminal facility of a carrier or intermediate handler.

"Transporting vehicle" means any truck, car, trailer, airplane, ship, or railroad car used for transporting animals.

"Weaned" means that an animal has become accustomed to take solid food and has so done, without nursing, for a period of at least 5 days.

"Wild animal" means any animal which is now or historically has been found in the wild, or in the wild state, within the boundaries of the United States its territories, or possessions. This term includes, but is not limited to, animals such as: Deer, skunk, opossum, raccoon, mink, armadillo, coyote, squirrel, fox, wolf.

"Wild state" means living in its original, natural condition; not domesticated.

"Zoo" means any park, building, cage, enclosure, or other structure or premise in which a live animal or animals are kept for public exhibition or viewing, regardless of compensation.

Done at Washington DC, this 7th day of March 1989.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 89-5611 Filed 3-9-89; 2:09 pm]

BILLING CODE 3410-34-M

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9 CFR Part 2

[Docket No. 88-014]

Animal Welfare Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This is a request for supplemental comments on the narrow issue of the interrelationship between Part 2 of the Animal Welfare Act regulations and our proposal to amend Part 3 of the regulations. We are proposing to amend the Animal Welfare regulations, 9 CFR Part 2. As part of our revision, we are proposing to add some new sections and revise others. New sections would provide regulations on Institutional Animal Care and Use Committees, Attending Veterinarians, and Veterinary Care. These amendments are necessary to comply with the amendments to the Animal Welfare Act (7 U.S.C. 2131, *et seq.*) ("Act") contained in Pub. L. 99-198, "The Food Security Act of 1985," enacted December 23, 1985. We are also proposing to add new sections on Holding Facilities and Handling to improve enforcement of the Act. We are proposing to revise other portions of the regulations in content and/or format to aid the public in understanding and using the regulations for the humane care, treatment, handling, and transportation of regulated animals. Rewriting the regulations is intended to make them easier to understand, thereby increasing compliance and making them more effective.

DATE: We will consider written comments addressing only the interrelationship of Parts 1 and 2 of the regulations with the proposed standards of Part 3, as explained in greater detail in the supplementary information which follows, that are postmarked or received on or before May 15, 1989.

ADDRESS: Send an original and three copies of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 1000, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 88-014. Comments received may be inspected at the APHIS Public Reading Room, Room 1141, U.S. Department of Agriculture, 14th and Independence Avenue, SW., Washington, DC, 8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. R.L. Crawford, Animal Care Staff, REAC, APHIS, USDA, Room 268, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7833.

SUPPLEMENTARY INFORMATION:

Background

In a document published in the **Federal Register**, on March 31, 1987 (52 FR 10298-10322), we proposed to revise the regulations contained in 9 CFR 2.1 through 2.130. These regulations pertain to licensing of dealers and exhibitors and registration of facilities and common carriers; recordkeeping for and identification of animals; holding periods and facilities; inspections; Institutional Animal Care and Use Committees; adequate veterinary care; and other areas relating to the humane care, handling, treatment, and transportation of animals. These changes have been proposed under the authority of the Animal Welfare Act (the Act), as amended (7 U.S.C. 2131, *et seq.*). They include some specific new requirements mandated by the 1985 amendments to the Act, contained in Pub. L. 99-198, "The Food Security Act of 1985," enacted December 23, 1985. The Act requires the Department to promulgate regulations and standards governing the humane handling, housing, care, treatment and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers. The standards and regulations must include minimum requirements with respect to handling, housing, feeding, sanitation, veterinary care, the use of pain relieving drugs, exercise for dogs, psychological well-being of nonhuman primates, recordkeeping, and other matters specified in section 13 of the Act, as amended (7 U.S.C. 2143).

We solicited comments concerning the proposal for a 60-day period ending June 1, 1987. The comment period was twice extended and ended on August 27, 1987. We did not consider comments and materials received after the closing date of August 27, 1987. We received a total of 7,857 comments addressing our proposal for Parts 1 and 2: 1,438 were

from the research community; 987 were from dealers and exhibitors; and 5,432 were from members of the general public. We included comments received from humane societies and groups representing the public in the areas of animal welfare and animal rights with comments received from the general public.

We received 344 comments (319 from the research community and 25 from members of the general public) stating that the Department should accord careful consideration to all of the comments received as required by the Administrative Procedure Act. We wish to assure the commenters, regulating persons, and members of the general public that the Department has carefully considered all of the comments that were received by the end of the comment period, and that we have revised the March 31, 1987 proposal on the basis of those comments where we considered it to be appropriate. These changes, discussed below, have been incorporated in this revised rule. We received much constructive input and appreciate the response.

Supplemental Request for Comments on the Interrelationship of Parts 1, 2, and 3 of the Animal Welfare Regulations

We received 334 comments (309 from members of the research community and 25 from members of the general public) suggesting that we revise the proposed rules for Parts 1 and 2, "Definition of Terms" and "Regulations," and publish a second proposal in the Federal Register for public comment. We also received 445 comments (400 from members of the research community and 45 from members of the general public) suggesting that we revise the proposals for Parts 1 and 2 and publish them along with our proposal for standards for the exercise of dogs and for a physical environment to promote the psychological well-being of nonhuman primates. These specific standards are mandated by the 1985 amendments to the Act.

We have decided to respond to the comments we received addressing the proposed rules, and to publish revised rules for Parts 1 and 2 in the same issue of the Federal Register in which we publish our proposal to amend Part 3 of the regulations, titled "Standards." The revised rules reflect our consideration of the nearly 8,000 comments received, our experience in administering and enforcing the regulations, and our ongoing consultation with the U.S. Department of Health and Human Services and other interested agencies. It is our present determination that upon their adoption as final rules, the revised provisions of Parts 1 and 2 conform with the requirements of the Animal Welfare Act, as amended.

Accordingly, we are publishing Parts 1 and 2 at this time, revised from our initial proposal, as explained in detail below. The revised rule for Part 2 contains specific regulations required by the 1985 amendments to the Act. These include regulations setting forth the responsibilities of Institutional Animal Care and Use Committees (IACUCs); requirements for Committee approval of animal care and use procedures in research involving animals; training by research facilities; use of pain relieving drugs; and inspection of animal use areas by the Committee. We believe that publication of the revised proposal for Part 2 concerning the administrative and institutional responsibilities of persons subject to the Act will assist the public in reviewing the proposed standards in Part 3 by placing the proposed standards in context. Also, many of the terms used in Part 3 are defined in Part 1, and a revised proposed rule containing definitions of those terms will aid the public in understanding the standards. The Department has decided upon this approach in the hope that it will answer many of the issues that would otherwise be raised in considering the standards contained in Part 3.

By way of example, we received 3 comments in response to proposed Part 2 (2 from dealers and 1 from a member of the general public) endorsing exercise for dogs and 13 comments (12 from dealers and 1 from a member of the general public) opposing mandatory exercise for dogs. One member of the general public commented in opposition to allowing dogs to be kept on tethers.

The requirements for exercise of dogs are directed by the Act (7 U.S.C. 2143(a)(2)(B)). They are contained in Subpart A of our proposed revision of Part 3, published elsewhere in this issue. (See companion docket no. 87-004.) We invite public comment in response to the proposed rule to amend Part 3.

At the urging of many commenters, we are publishing the revised rules for Parts 1 and 2 for the sole purpose of soliciting comments on tha narrow issue of the interrelationship of the definitions and regulations in Parts 1 and 2 with the standards we are proposing in Part 3. The public is therefore invited to comment exclusively on this issue. We will not consider comments going beyond this issue.

Comments raising objections or suggesting changes to the March 31, 1987 proposal are discussed below in this supplementary information. Due to the length of this document and the scope of the issues addressed, subheadings are provided in the supplementary information to guide the reader through the material. Section numbers are used in the subheadings wherever possible to further assist the reader. We have provided the number of comments received and their source (e.g., research community, members of the general public) pertaining to each section because this information may be of interest to some readers. Except as explained in this supplementary information, the provisions of the March 31, 1987 proposal have been included in this revised rule for the reasons set forth in that proposal.

In our discussion of the comments we received, we refer to both the proposed rule published March 31, 1987 and to this revised proposed rule. In order to assist the reader in distinguishing between these two documents, we use the terms "proposed" or "proposal" when referring to the March 31, 1987 proposed rule. We use the terms "revised" or "revision" when referring to this revised rule.

In the supplementary information to proposed Parts 1 and 2, we stated that, based upon the information available to the Department, the proposed rules were issued in conformance with Executive Order 12291 and Secretary's Memorandum No. 1512-1, and that they had been determined not to be "major rules" (52 FR 10295 and 10307). We also stated that the information collection provisions included in proposed Part 2 had been submitted for approval to the Office of Management and Budget (OMB) (52 FR 10307) and that proposed Part 1 contained no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, *et seq.*). We further stated that the proposed rules would not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act (52 FR 10295 and 10307-10308).

We received 851 comments (825 from the research community, 25 from members of the general public, and 1 from a dealer) stating that the Department should perform the regulatory analyses required for: (1) A "major rule" under Executive Order 12291; (2) determining the impact on small entities in accordance with the Regulatory Flexibility Act; and (3) the Paperwork Reduction Act. Commenters demanded that we consider in our analysis the burden of administrative requirements required of the attending veterinarian and the Institutional

Animal Care and Use Committee under the proposal. We received 861 comments (834 from the research community, 1 from an exhibitor, and 26 from members of the general public) stating their disagreement with our statement that the proposed regulations are not a "major rule" under Executive Order 12291 and that the regulations would not impose significant financial burdens on registrants and licensees.

In conducting the regulatory analyses referenced above, we considered Parts 1 and 2 separately. The determinations we made were preliminary ones. Now, with more information available to us, including the comments we received, we have determined to consider the combined impact of Parts 1, 2, and 3. We have determined that, considered together, the rules for Parts 1, 2, and 3 are a major rule. A discussion of the regulatory analyses performed appears under the headings, "Executive Order 12291," "Regulatory Flexibility Act," and "Paperwork Reduction Act."

General Comments

We received 939 comments (910 from members of the general public, 25 from the research community, 3 from exhibitors, and 1 from a dealer) expressing general support for the proposed regulations. We also received 296 comments (295 from members of the general public and 1 from the research community) in support of the proposed regulations and stating that the Department should not lessen them due to pressure from associations for biomedical research. We received 256 comments (189 from members of the general public, 44 from the research community, 16 from dealers, and 1 from an exhibitor) expressing general opposition to stronger regulations. We also received many comments expressing specific objections to the proposed regulations.

We received 1,060 comments (1,034 from the research community and 26 from members of the general public) stating that the proposed rules exceed our statutory authority under the Act and are not consistent with the intent of Congress. We disagree with these comments and believe that ample statutory authority exists for these regulations. In the supplementary information which follows, we respond to those comments challenging our statutory authority for specific provisions of the regulations and our carrying out of congressional intent.

We received 613 comments (588 from the research community and 25 from members of the general public) stating that the Department did not coordinate with the Secretary of Health and Human Services (HHS) in issuing the proposed regulations, as required by the Act. Section 15 of the Act directs that:

> [t]he Secretary shall consult and cooperate with other Federal departments, agencies, or instrumentalities concerned with the welfare of animals used for research, experimentation or exhibition, or administration of statutes regulating the transportation in commerce or handling in connection therewith of any animals when establishing standards pursuant to section 13 and in carrying out the purposes of this Act. The Secretary shall consult with the Secretary of Health and Human Services prior to issuance of regulations. (7 U.S.C. 2146(a)).

The Department did consult extensively with HHS. On numerous occasions before issuing the proposed regulations, we discussed the issues with HHS representatives and provided HHS with copies of each draft of our proposal for review and comment. HHS indicated its concurrence with the proposed regulations. In evaluating the comments received in response to the proposal and in preparing this revised rule, we have consulted extensively and on an ongoing basis with HHS. A representative from The National Institutes of Health was detailed to work with APHIS and to provide the HHS position on all issues affecting the research community that were raised by the commenters. We also convened a meeting with representatives of HHS to discuss and resolve outstanding differences between HHS and the Department. Through this give and take we achieved what we understand to be a mutually satisfactory resolution of many of our outstanding differences. We believe that this revised rule is reasonable and, based upon our ongoing communication with HHS, that it could be readily implemented in the research community.

We received 106 comments (105 from the research community and 1 from a member of the general public) stating that the regulations as proposed would be inconsistent with other federal regulations. We disagree with the import of this characterization. We believe that any remaining differences between Parts 1 and 2 of the Animal Welfare regulations, as revised, and those related regulations of other agencies, particularly those of HHS, are necessitated by requirements contained in the Act. As stated in the preceding paragraph, we have attempted to reconcile differences between HHS and the Department. Our regulations must, however, fulfill the mandate of Congress and must be authorized by the Act, as amended.

We received 1,004 comments (979 from the research community and 25 from members of the general public) objecting to the proposed regulations on the grounds that they would interfere with or impede research. The Department has remained especially sensitive throughout the rule-making process to this issue. Congress stated in the 1985 amendments that "[n]othing in [the] Act (i) except as provided in paragraph (7) of [subsection (a)] shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such facility; (ii) except as provided * * * shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility; * * *" (7 U.S.C. 2143(a)(6)(A) (i) and (ii)). Paragraph (7) of subsection (a) provides that the Secretary will require each research facility to show upon inspection and to report at least annually that it is in compliance with the Act and that professionally acceptable standards governing the care, treatment, and use of animals are being followed during research or experimentation. It also requires the research facilities to provide information and assurances concerning painful procedures, and an explanation for any deviation from the standards promulgated under section 13(a) of the Act (7 U.S.C. 2143(a)(7)). Nevertheless, the Act imposes new responsibilities upon research facilities, as well as others subject to the Act, which necessarily impact upon the internal workings of research facilities. There are some costs necessarily associated with changes of this kind. Regulated persons who must alter their internal procedures and structure and their lines of reporting and responsibility to accommodate the 1985 amendments to the Act may feel that the regulations impose an undue burden. We believe, however, that the burdens imposed on research facilities are statutorily required and are reasonable in order to effectuate the purposes of the Act and the 1985 amendments to the Act, and that they are the minimum necessary to accomplish those goals.

We received 315 comments (290 from the research community and 25 from members of the general public) stating that APHIS has failed to show a rational connection between the proposed rules and the agency record. We have been charged with the responsibility of administering and enforcing the Animal Welfare Act since it was enacted in 1966. Our experience has revealed areas

in which more stringent regulations are necessary. The supplementary information contained in the March 31, 1987 proposed rule and in this revised rule highlight areas where additional regulatory efforts have proven necessary. These revised regulations provide mechanisms designed to prevent circumvention of the Act and the regulations and to assist the Department in its enforcement efforts. They are based either on the 1985 amendments to the Act or on the Department's experience in enforcing the regulations. We believe these revisions would better effectuate the intent of Congress to promote animal welfare.

We received 622 comments (597 from the research community and 25 from members of the general public) stating that the proposed regulations improperly enlist Institutional Animal Care and Use Committees and attending veterinarians as enforcement agents of the federal government, and 1 comment from a member of the research community in support of their use as Department agents. The duties of the Committee and the attending veterinarian at research facilities are more fully described in this supplementary information under the discussion of Subparts C and D, "Institutional Animal Care and Use Committee and Other Requirements for Research Facilities" and "Attending Veterinarian and Adequate Veterinary Care." We note that responsibility for compliance with the Act and the regulations and for providing necessary assurances has always rested with the institutions and with the legally responsible institutional officials. Many of their duties can most effectively be carried out through the Committee and the attending veterinarian acting as agents of the facility and its officials, since the Committee and attending veterinarian are usually in the best position to determine whether the research facility is in compliance. For this reason, the Act imposes many oversight and supervisory responsibilities on them. We believe that the reassignment of responsibilities to the research facility from the Committee and attending veterinarian in Subparts C and D of this revised rule clarifies our intent that institutions act through them while remaining ultimately responsible.

We received comments from 105 members of the general public opposing the use of animals for research altogether. We have made no changes based on these comments. It would be beyond our authority to ban the use of animals in research. Our regulations are authorized by the Act, and the Act specifically states that "the use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals; * * *" (7 U.S.C. 2131(b)).

Seventy-four commenters (72 from the research community and 2 dealers) stated that the proposed regulations are poorly organized and written, and that clarification is needed. We believe that this supplementary information and the revised proposed rule that follows provides the necessary reorganization and clarification.

Two commenters from the research community stated that APHIS will be unable to enforce the regulations. We disagree with the commenters based upon the Department's enforcement record. Congress has entrusted the Department with enforcement of the Animal Welfare Act and with the promulgation and enforcement of regulations under the Act since the Act's enactment in 1966. We will continue our best efforts to meet this responsibility and to perform in accordance with the mandate of Congress.

Subpart A—Licensing

We received 295 comments (270 from the research community and 25 from members of the general public) generally endorsing the proposal regarding Subpart A.

Section 2.1 Requirements and application

Proposed § 2.1 sets forth who must obtain a license under the Animal Welfare regulations and provides the application procedure for obtaining a license. It details the information which an applicant must provide and where an applicant must file to become licensed. This section also provides the application fee and renewal application fee. (Annual license fees are provided in proposed § 2.6.) Exemptions from the requirement to be licensed are included in this section along with a provision for obtaining a voluntary license in very limited circumstances. Renewal procedures are provided and grounds for denial, suspension, or revocation of a license are included in this section as well. Grounds for denial of an initial license application are addressed in detail in proposed § 2.11.

Before addressing the comments received concerning proposed § 2.1, we note the following clarifications we are making in this revised rule. First, proposed § 2.1(a)(1) would require that:

> Any person, 18 years of age or older, operating or desiring to operate as a dealer, exhibitor, or operator of an auction sale except persons who are exempted from the licensing requirements under paragraph 3 of this subsection, must have a license.

We are concerned that this provision could be misconstrued as allowing a person under 18 years of age to operate as a dealer, exhibitor, or operator of an auction sale without having to obtain a license. We believe that most readers understand that persons must be at least 18 years of age to be eligible to obtain a license to operate as a dealer, exhibitor, or operator of an auction sale, and that a license is required to operate in those capacities. The intent underlying the minimum age requirement was stated in the supplementary information to the proposed rule. We have revised the final rule to reflect our intent more accurately.

Second, under § 2.5, as revised in this rule, licenses are valid and effective unless they are terminated, suspended, or revoked, or expire at the end of the 1-year term. The proposed rule provided that licenses would be valid and effective for 1 year, and did not distinguish between initial license applications and applications for additional 1-year terms. We have made conforming changes throughout Subpart A to differentiate between new license applications and license renewals. Accordingly, proposed § 2.1(a)(2) is revised to require an applicant for renewal of a license to indicate all premises, facilities, or sites where animals are kept or the licensee operates on the application for renewal. We are also replacing "termination date" with "expiration date," wherever it is used to mean the calendar end of the 1-year license term, as in § 2.1(e).

Section 2.1 of the current regulations provides that persons who are exempt from the licensing requirement under section 3 of the Act do not have to apply for a license to operate as a dealer, exhibitor, or operator of an auction sale where dogs or cats are sold affecting commerce. We proposed to revise § 2.1 by identifying those persons exempt from the licensing requirements under section 2 or section 3 of the Act.

We received 35 comments pertaining to § 2.1, as proposed. Four commenters from the general public stated that proposed § 2.1 would allow too many exemptions from the requirement to obtain a license. Section 2 of the Act (7 U.S.C. 2132(f)) defines the term "dealer" as:

> any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a

carrier, buys, or sells, or negotiates the purchase or sale of, (1) any dog or other animal whether alive or dead for research, teaching, exhibition, or use as a pet, or (2) any dog for hunting, security, or breeding purposes, except that this term does not include—(i) a retail pet store except such store which sells any animals to a research facility, an exhibitor, or a dealer; or (ii) any person who does not sell, or negotiate the purchase or sale of any wild animal, dog, or cat and who derives no more than $500 gross income from the sale of other animals during any calendar year;

The regulatory exemptions proposed are either statutorily mandated or are in accordance with the intent of the Act, which is to regulate the commercial use of animals, other than their use as food or fiber.

Twelve dealers stated that the proposed exemptions from the licensing requirement for retail pet stores and for persons who maintain three or fewer breeding female dogs or cats and who sell the offspring born and raised on their premises for pets or exhibition would be improper. The Act requires that dealers and exhibitors must be licensed, and specifically provides that "any retail pet store or other person who derives less than a substantial portion of his income (as determined by the Secretary) from the breeding and raising of dogs or cats on his own premises and sells any such dog or cat to a dealer or research facility shall not be required to obtain a license as a dealer or exhibitor under this Act." (7 U.S.C. 2133). As defined in the Act, the term "dealer" does not include retail pet stores, except those which sell any animals to a research facility, exhibitor, or a dealer (7 U.S.C. 2132(f)). Accordingly, the proposed exemptions are statutorily required and will continue to be included in the regulations.

We are making a change in proposed § 2.1(a)(3)(i) to delete mink from the listing of pet-type animals which retail pet stores can sell and still be exempt from the licensing requirement. This change is in accordance with the revised definition of "retail pet store" in the revised rule for Part 1— "Definition of Terms," published elsewhere in this issue. (*See* companion docket no. 88–013.)

We are also correcting proposed § 2.1(a)(3)(iii) to read "Any person who maintains a total of three (3) or fewer breeding female dogs and/or cats * * *." This section is intended to exempt the hobby breeders who derive less than a substantial portion of their income from the breeding and sale of dogs or cats, in accordance with section 3 of the Act (7 U.S.C. 2133). The correction would clarify that a person having a combined total of three or fewer breeding female dogs, or three or fewer breeding female cats, or three or fewer breeding female dogs and cats qualifies for exemption from the licensing requirement, not a person having three or fewer breeding female dogs and three or fewer breeding female cats.

We are similarly correcting proposed § 2.1(a)(3)(iv) to read "Any person who sells fewer than 25 dogs and/or cats per year * * *." This section is intended to exempt persons who derive less than a substantial portion of their income from the breeding and raising of dogs and cats, and we have determined that the sale of a combined total of fewer than 25 of these animals would qualify a person for this exemption. The correction clarifies that a person selling fewer than 25 dogs, or 25 cats, or 25 dogs and cats qualifies for exemption from the licensing requirement, not a person selling fewer than 25 dogs and fewer than 25 cats.

We are making an additional change in proposed § 2.1(a)(3)(iv) to include terms which were inadvertently omitted from the proposal. The words "teaching, or testing" are added between "research" and "purposes" in the revised rule to make clear that the exemption for sales of fewer than 25 dogs and/or cats applies to sales for research, teaching, and testing purposes, in accordance with the purposes of the Act.

Five commenters (2 dealers, 1 exhibitor, and 2 members of the general public) stated that an additional exemption from the requirement to obtain a license for federal, state, and local parks with free roaming herds of animals native to the area which utilize auctions as part of a herd size control program should be added to the regulations. The legislative history of the Act indicates that the term "dealers" as used in the Act is limited to private persons and entities and nonprofit or charitable institutions, and does not include federal agencies or political subdivisions of state or local governments. (*See* Conference Report No. 1848, at p. 9, August 11, 1966.) There is no authority under the Act to license federal, state, and local governments as dealers, and accordingly no exemptions for them have been provided.

One dealer commented that the licensing requirements should be less stringent and should allow more exemptions, such as for brokers and for sales through classified ads and publications. The Act includes brokers in the definition of "dealer" by referring to any person who "negotiates the purchase or sale" of any of the covered animals and we are statutorily required to license these persons. Furthermore, the Act does not provide an exemption from the licensing requirements for sales accomplished through classified ads and publications. These sales are "in commerce" and are subject to the Act and regulations. The medium through which a sale is accomplished is irrelevant so long as it is in commerce. We do not regulate classified ads or publications; however, we can and do use them to find persons who should be licensed in accordance with the regulations.

One commenter from the research community sought clarification of the licensing requirements applicable to research facilities selling animals. Research facilities acting as dealers are subject to the same regulations as any other dealer and must be licensed in accordance with § 2.1, unless they are a department, agency, or instrumentality of the United States, or of a state or local government, in which case they need not obtain a license.

Three dealers commented that the Department should require anyone selling animals at auction sales to obtain a license. We have found that many individuals sell a number of animals at auctions during the course of a year. We believe that the proposed exemptions are consistent with the Act and provide appropriate threshold points for the imposition of the requirement to obtain a license. Moreover, budgetary and personnel restrictions would prevent us from being able to regulate effectively all of these persons.

Similarly, we disagree with the 3 commenters from the general public who stated that the Department should require licensing of all persons who sell or trade animals at flea market operations. The legislative history of the Act makes clear that the licensing requirement was intended to regulate the commercial sale or use of animals as part of a business concern. Some animal sellers at flea markets sell animals as part of a commercial operation, but many others sell them for use as pets or for personal enjoyment. The proposed licensing requirements and exemptions will still require large volume or commercial sellers to obtain a license.

Three commenters from the research community stated that the Department should delete the requirement that persons who sell exotic or wild animals be licensed as dealers. Licensing of these persons is statutorily mandated (7 U.S.C. 2132(f)).

One research facility objected to the imposition of dealer licensing requirements on sellers of small

quantities of wild animals since research facilities would not be able to purchase small quantities of non-domesticated species from an unlicensed source. The definition of "dealer" in the Act permits an exemption based on dollar amount of sales only for those persons who do not sell wild animals (or dogs or cats) and therefore persons who sell wild animals must be licensed, regardless of the number of animals they sell (7 U.S.C. 2132(f)(ii)). We require research facilities to purchase these animals from licensed sources, in accordance with the Act.

Proposed § 2.1(b) would eliminate voluntary licenses, except for persons who sell fewer than 25 dogs or cats per year for research or teaching purposes. This will prevent people from trying to circumvent certain state and local community laws concerning keeping dangerous animals. We received 2 comments from dealers objecting to the restricted grounds for issuance of voluntary licenses, and suggesting that people who buy only 1 or 2 animals as pets or for breeding purposes would have to buy their animals from a licensed dealer, possibly at higher prices. One commenter from the general public commended us for this provision. We believe the dealers' concern is misplaced. It is not the intent of the Act or of the Department to regulate the acquisition of private pets or animals for personal use and enjoyment

Broader use of voluntary licenses requires greater use of the Agency's limited resources and personnel, which could be utilized more effectively by focusing on animals used in commercial or research operations. The regulation for voluntary licenses remains as proposed, except that reference to the $10 application fee and a provision for annual license fees is included in paragraph (b) for clarification. Reference to the renewal fee for voluntary licenses is also included in § 2.1(e)(1) of the revised rule. Annual license fees are provided in § 2.6 of the regulations for Class "A," Class "B," and Class "C" licensees. However, the proposed regulations inadvertently did not require license fees for voluntary licensees, who, by definition, do not qualify for licensing under any of the Classes. Voluntary licensees operate most like Class "A" licensees, except that they are exempt from the licensing requirements. Accordingly, the annual license fee for a voluntary license would be that of a Class "A" licensee (breeder) under this revised rule.

Five commenters (4 exhibitors and 1 dealer) commented that we should eliminate the $10 application fee for license renewals required by proposed § 2.1(e) and 1 exhibitor suggested having a one-time application fee for the initial license application required by proposed § 2.1(d), instead of the annual $10 application fee. We believe that it is more equitable to charge licensees on a yearly basis to cover annual processing costs, since a one-time fee could overcharge some and undercharge others.

The $10 application fee is also required when a licensee applies for a change in the class of license from that issued to him or her, such as a change from a Class "A" to a Class "B" license. This is necessary because a change in class requires administrative processing that is similar to processing a new application or a renewal application. We have redesignated proposed paragraph (e) as (e)(1) in the revised rule. We have added a new paragraph (e)(2) to the revised rule and revised § 2.6(a) ("Annual licensee fees") to clarify this requirement.

We have revised § 2.1(e)(1) to require licensees to submit a completed application form with their $10 application fee. We believe that it is necessary specifically to require submittal of this form along with the fee since many licensees overlook it.

Section 2.2 Acknowledgement of regulations and standards

We are revising § 2.2 so that it applies to applications for license renewals, as well as to initial license applications. This change is necessary to conform with § 2.5, as revised in this rule, which provides that licenses are valid and effective if renewed, unless terminated, suspended, or revoked.

Section 2.3 Demonstration of compliance with standards and regulations

For the reasons outlined above under the discussion of § 2.1, we are revising proposed § 2.3 in this rule so that it includes applications for license renewals, as well as initial license applications. Accordingly, we have revised paragraph (a) to require that each applicant for a license or renewal of a license must demonstrate compliance with the regulations and standards in Parts 2 and 3 of Subchapter A. We have removed the words, "before a license will be issued" from the requirement because it applies to both initial licenses and license renewals. We have revised paragraph (b) to clarify that it only applies to initial license applications.

We are revising § 2.3(a) to require each applicant to make his or her animals, premises, facilities, vehicles, equipment, other premises, and records available for inspection by APHIS officials during business hours, and at other times mutually agreeable to the applicant and APHIS, rather than "and/or at other times" as proposed. We believe this revision is necessary to prevent licensees from avoiding inspections by being unable to agree to a time with APHIS officials.

We received three comments (2 from the general public and 1 from the research community) expressing support for this section as proposed. Two dealers commented that we should limit the number of opportunities an applicant has for inspection to demonstrate their compliance with the regulations and standards and 1 also commented that applicants should be required to pay the cost of re-inspection. (Demonstration of compliance is a prerequisite to issuance of a license.) We believe this suggestion has merit and that a limit on inspections should be incorporated in the regulations. This section is revised to impose a limit of three pre-licensing inspections. If the applicant is unable to pass inspection after 3 attempts he or she will forfeit the application fee, to help cover the administrative cost of processing their application and the cost of the inspections, and will be ineligible to reapply for a license for a period of 6 months following their last inspection. As is the case for the prior inspections, the applicant will be advised of deficiencies and the necessary corrective measures that must be taken to comply with the regulations and standards, and accordingly to pass inspection. We believe that allowing an applicant 3 opportunities to pass inspection is reasonable, since it would give the applicant notice of any deficiencies found by an inspector and a second chance to rectify any remaining deficiencies found after re-inspection. We also believe that if an applicant is unable to pass inspection after 3 attempts, 6 months provides sufficient time to enable him or her to take the necessary corrective measures which he or she has been unable to provide between the 3 failed inspections.

We are not incorporating the suggestion that licensees pay the cost of re-inspections. The initial application fees and annual fees are intended to help the federal government defray the cost of program operations. We believe that the fees we have assessed are reasonable and equitable for the nature of the operations being licensed, and have determined at this time that additional fees are not appropriate.

Section 2.4 Non-interference with APHIS officials

Under proposed § 2.11(a), APHIS would deny a license to any applicant who "(6) [h]as interfered with, threatened, abused (including verbal abuse), or harassed any [APHIS official] in the course of carrying out his or her duties." As explained below under the subheading, "§ 2.11 Denial of license," and in the supplementary information to the proposal of March 31, 1987, at 52 FR 10300, we explain that we have determined the need to include in the regulations a prohibition against interference with APHIS officials. Also, as explained in greater detail below under that subheading, § 2.11 applies to denial of initial license applications only in this revised rule, and not to renewals. Based on our experience in enforcement efforts, we have determined that it is necessary to require licensees to comply with the prohibition against interference and harassment of APHIS personnel, as well as new applicants. We are therefore removing paragraph (a)(6) from § 2.11 in the final rule and are including its provisions as § 2.4 in the revised rule so that it is applicable to both initial license applicants and licensees.

Section 2.5 Duration of license and termination of license

We did not receive any comments regarding this section as proposed. We are revising § 2.5, however, to clarify that licenses are valid and effective if renewed each year and have not been terminated, suspended, or revoked. Similarly, we are revising proposed paragraph (b) to refer to an application for license renewal. These amendments are necessary to avoid any misconception that every license automatically terminates at the end of its 1-year term and that each year an applicant must follow the procedure applicable to obtaining an initial license. For this reason, and as previously stated, we are replacing the word "termination" with "expiration" in § 2.5 and all of Subpart A wherever it refers to the calendar end of the 1-year license term.

We are making one correction to § 2.5(b) to specify that a licensee will be notified by "certified" mail, rather than first class mail, of the expiration date of a license, to ensure that all licensees have notice that they must renew their license or it will automatically terminate because it has expired. Except for nonsubstantive changes made for clarification, the remaining provisions of this section remain as initially proposed.

Section 2.6 Annual license fees

We received a number of comments addressing the proposal to increase license fees. Thirty-seven dealers expressed opposition to yearly license fees in general. Charging license fees is statutorily mandated. Section 23 of the Act directs the Secretary to charge and collect reasonable license fees "adjusted on an equitable basis taking into consideration the type and nature of the operations to be licensed * * *" (7 U.S.C. 2153).

Nine commenters from the general public and 6 dealers indicated their general support for the increased license fees. One member of the general public stated that the increases were too low. We received 48 comments (32 dealers, 12 exhibitors, and 4 members of the general public) stating that some fee increase is justified, but that the increases we proposed are too high or too drastic a change from the current fee tables. We received 298 comments (273 from the research community and 25 from members of the general public) stating concern that the fee increases could discourage some small dealers from becoming licensed. We have reconsidered the proposed fee structure in light of those comments and are revising them downward as follows: (For ease of comparison, the proposed fees are indicated in parentheses, and the revised fees are indicated without parentheses.)

TABLE 1.—DEALERS, BROKERS, AND OPERATORS OF AN AUCTION SALE—CLASS "A" AND "B" LICENSES

Over	But not over	(Fee)	Fee
$0	$500	$(50)	$30
500	2,000	(100)	60
2,000	10,000	(200)	120
10,000	25,000	(400)	225
25,000	50,000	(600)	350
50,000	100,000	(800)	475
100,000		(1,000)	750

TABLE 2.— EXHIBITORS—CLASS "C" LICENSE

Number of animals	(Fee)	Fee
1 to 5	$(50)	$30
6 to 25	(125)	75
26 to 50	(250)	175
51 to 500	(375)	225
501 and up	(500)	300

We believe these fees are a reasonable increase over the existing fees, and that they are equitably adjusted for the different classes of licensees and for the ranges in dollar volume of business derived from transactions involving animals.

We have removed proposed paragraph (b)(4) from § 2.6 in the revised rule because it could be construed as implying that a dealer can operate without a license. This is not the case. Only persons exempt from the licensing requirements may operate without a license, as provided in § 2.1(a)(3). Proposed paragraphs (b) (5) and (6) are redesignated as paragraphs (b) (4) and (5) in this revised rule.

We are revising paragraphs (b) (1) through (5) to clarify that paragraphs (b) (1) through (3) are applicable to license renewals, paragraph (b)(4) is applicable to initial licenses, and paragraph (b)(5) is applicable to both initial licenses and license renewals.

We received 8 comments (4 from exhibitors, 3 from members of the general public, and 1 from a dealer) regarding the division of fees between the lessor and lessee of animals, as provided by proposed § 2.6(b), paragraphs (1), (2), and (5), stating that either the lessor or lessee should be responsible for including the revenue from a leased animal in determining their annual fee, but not both. We disagree with these comments since both the lessor and lessee derive income from the leased animals. There are two income streams resulting from use of a leased animal, and both business operations are required to pay a fee which is equitable for the nature and type of operation it is. Also, both the lessor and lessee are licensed, and thereby impose costs on the Department to ensure compliance with the regulations and standards. We believe it is proper to require both the lessor and lessee to include their respective income from an animal in determining their annual fee.

We also received 4 comments from the research community and 2 from members of the public suggesting the need to code animals leased to research facilities as a tracing mechanism to ensure that the animals are not used for more than one major operative procedure from which they are allowed to recover. We consider this requirement to be unwarranted since, to the best of our knowledge, animals are rarely, if ever, leased for research purposes. We are not making any changes in § 2.6 based upon this comment.

We are making one change in paragraph (d) for clarification. Paragraph (d) provides that if a person meets the licensing requirements for more than one class of license, he must pay the fee for his predominant type of

business, as determined by the Secretary. The clarification will add that in addition to the fee paid, the class of license that person must obtain will be determined by his or her predominant type of business, since a person cannot have more than one license in accordance with § 2.1(c). The words "obtain a license and" are added following "he shall be required to." We are revising the rule to refer to both masculine and feminine genders. Accordingly, "he" is replaced with "he or she" in § 2.6(d) and throughout the revised rule. Similarly, "his" is replaced with "his or her" wherever it appears.

Section 2.7 Annual report by licensees

We are revising proposed § 2.7 to clarify that it applies to license renewals only, and not to initial license applications.

Proposed § 2.7(a) would provide as follows:

> Each year, within 30 days prior to the termination date of his/her license, a licensee shall file with the Area Veterinarian in Charge an application for license and annual report upon a form which will be furnished to him upon request to the Area Veterinarian in Charge. When the requirements of §§ 2.1, 2.2, 2.3, and 2.6 have been met, the license will be issued subject to the exceptions in §§ 2.5, 2.10, and 2.11.

We are revising proposed § 2.7(a) to refer only to license renewals and the requirement that licensees submit an annual report in order to renew their license. In this revised rule, we refer to the expiration date of the license and have replaced "license" with "license renewal." We are also removing the last sentence of proposed § 2.7(a) because it refers to requirements applicable to issuance of an initial license, and these are set forth in § 2.1(d).

Three dealers and 1 exhibitor commented that clarification is needed concerning requirements to include statements about young animals in their annual reports and in other reports. The requirement to identify all dogs and cats when obtained or when weaned is set forth in proposed § 2.50. All animals must be identified in the licensee's records at his or her facility when born or obtained from outside the premises, in accordance with proposed §§ 2.75 and 2.77. Proposed § 2.7(d) would require exhibitors (Class "C" licensees) to include in their annual report the number of animals owned, held, or exhibited by the licensee either during the previous year or at the time of signing the annual report, whichever is greater. The figure used must include all animals regardless of age, and is the basis for determining the Class "C" license fee. We do not believe this requirement needs further elaboration in the regulations.

We received 8 comments (4 exhibitors, 3 dealers, 1 from the research community) objecting to the requirement provided in proposed § 2.7(e) for licensees to have the attending veterinarian certify in the licensee's annual report that the attending veterinarian understands the regulations and standards under the Act, and that he or she has visited the premises and carried out the responsibilities indicated in the regulations and in the written program of adequate veterinary care. The commenters stated that the requirement to have a written program of veterinary care as provided in proposed § 2.40 is sufficient. We agree that the attending veterinarian should not be required to sign the licensee's annual report in light of the requirements in proposed § 2.40 that licensees maintain a written program of adequate veterinary care which is subject to inspection at the licensee's facility and is sent to the Area Veterinarian in Charge each year. We have therefore deleted this requirement from the revised rule.

Section 2.8 Notification of change of name, address, control, or ownership of business

We have made one correction in this section. The phrase "or by any additional sites" should read "or of any additional sites * * *." We received no comments addressing this section and have made no other substantive changes.

Section 2.10 Licensees whose licenses have been suspended or revoked

Two dealers commented in opposition to our proposal to make license revocations permanent. We were urged to allow the facts and circumstances surrounding the offense leading to revocation to be taken into consideration in determining the appropriate amount of time a former licensee must wait before he or she could apply for a new license, instead of being permanently ineligible. We disagree with these comments. Whether a license should be suspended or revoked is determined after notice and a hearing. Testimony as to the facts and circumstances surrounding the offense would be brought out at the hearing. In such an administrative proceeding conducted in accordance with the Department's Rules of Practice, revocation would be ordered for serious offenses which are determined to warrant this sanction, as compared to suspension, which could be ordered for a stated period of time for less serious offenses. We believe that the commenters' concerns that the facts and circumstances be considered would be amply addressed in the required hearing. Accordingly, revocation of a license will remain a permanent sanction. As discussed below under the next subheading, we are adding to § 2.10(a) the provision from proposed § 2.11(b) stating that any person whose license has been suspended may reapply for a license after the period of suspension is ended. We are revising it, however, to provide that any person whose license has been suspended may apply to the Area Veterinarian in Charge, in writing, for reinstatement of his or her license, rather than having to reapply for a new license. No other substantive changes are made in this section.

Section 2.11 Denial of license

The comments we received addressing proposed § 2.11 deal principally with existing licenses, convincing us of the need to separate the provisions concerning denial of initial license applications from provisions concerning suspended or revoked licenses. We are discussing those comments in this discussion of "§ 2.11, Denial of license," since readers who are more interested in the substance of proposed § 2.11 than that of § 2.10, and who may have commented specifically with regard to § 2.11, may look to this heading for our response instead of the heading, "§ 2.10 Licensees whose licenses have been suspended or revoked."

Many of the comments we received concerning proposed § 2.11 addressed due process issues which would be raised if we suspended or revoked a license. As should be clear from the supplementary information, paragraph (a) and most of paragraph (b) of this section are concerned with denial of initial license applications, and do not have any bearing on suspension or revocation of existing licenses. We have renamed this section "Denial of initial license applications" to avoid any further confusion.

Paragraphs (b) and (c) refer to both suspended licenses and denials of license applications. For purposes of clarity, we are removing the reference to suspended licenses from § 2.11. Accordingly, paragraphs (b) and (c) will address denial of initial license applications exclusively. The content of proposed § 2.11(b) with regard to suspended licenses has been added to § 2.10(a) in the revised rule, and that of § 2.11(c) is already contained in § 2.10(a) so there is no need for further revision.

We received several comments objecting to the proposed reasons for which we would deny a license application and to this section in general. Thirty-three commenters from the research community stated that a plea of nolo contendere (no contest) under state or local cruelty to animals laws within 1 year of application for a license should not be an automatic basis for denial of a license, since a licensee may elect to enter this plea rather than a plea of not guilty, to avoid the time and expense of a full hearing on the charge. In light of this comment, we are revising the rule to provide that if no penalty is imposed as a result of a plea of nolo contendere, the applicant may reapply immediately without having to wait a year. We believe this will accommodate those persons who exercise their rights to enter this plea, while allowing the Administrator to deny a license to persons involved in violations of the cruelty to animals laws.

We received 366 comments (321 from the research community, 11 from dealers, 7 from exhibitors, and 27 from members of the general public) opposing subparagraph (6) as a basis for denial of a license. A similar prohibition against interfering with, threatening, abusing, or harassing any APHIS official in the course of carrying out his or her duties is provided in § 2.4 in the revised rule. Accordingly, we have added § 2.4 to § 2.11(a)(1) in the revised rule so that it remains a basis for denial of a license. As proposed, subparagraph (6) would provide that a license will not be issued to any applicant who "[h]as interfered with, threatened, abused (including verbal abuse), or harassed any Veterinary Services inspector in the course of carrying out his/her duties." The comments stated that this is too ambiguous and subjective a basis for denying or revoking a license. We are retaining this basis for denial of a license because we have determined a geuuine need for it, based upon our experience in enforcing the regulations. First, adequate safeguards against subjective determinations are contained in § 2.11(b) as proposed. which provides that an applicant whose application is denied may request a hearing in accordance with the applicable rules of practice. At a hearing, the Department would have to support its denial of an application in accordance with the rules of practice and would have to show that it is reasonable and not arbitrary and capricious. We believe this is sufficient to avoid subjectivity or arbitrariness from entering into the determination. Second, § 2.11 applies to denial of an application for a license, not suspension or revocation of an issued license. Suspension and revocation procedures include notice and hearing and must satisfy the requirements of due process of law.

We received 318 comments (282 from the research community, 10 dealers, and 26 members of the general public) objecting to proposed paragraph (b) of § 2.11 which provides that the denial of a license would remain in effect until a final legal decision is made following a hearing, on the basis that this could deprive a person of their livelihood for years before they receive the benefit of due process of law.

As explained above, this section applies to initial license applications, not to renewals of existing licenses. Suspension and revocation of an issued license would be in accordance with the requirements of the applicable Departmental rules of practice. Except as previously noted, paragraph (b) remains as initially proposed.

We received 303 comments (278 from the research community and 25 from members of the general public) objecting to proposed § 2.11(c), which provides that a legal entity in which a person whose license application has been [suspended or] denied has a substantial interest, financial or otherwise, will not be licensed within 1 year of the denial [or until completion of the suspension period]. (The bracketed provisions refer to suspended licenses and are contained in § 2.10(a) in the final rule).

One commenter was concerned that the regulation as proposed could prevent a facility from being licensed for a year simply because one of its shareholders had been denied a license. We do not believe this concern is well-founded, as the regulation is limited to legal entities in which a person whose application has been denied has a "substantial" interest. This may or may not apply to a shareholder, depending upon that person's interest. We do not agree with the commenter that the proposed restriction should apply only if that person has a "substantial interest, financial or otherwise, and responsibility for the operation or management of the applicant." Licenses can be issued at the lowest level of legal entity, that is, to individuals. Any person who was engaged in activity serious enough to warrant denial of a license application should not be allowed to continue in operation under the umbrella of another legal entity in which they can exercise *any* measure of control and can influence operations. This is what the proposed regulation is intended to prevent. A similar provision has been included in the regulations since 1970 without problems or objections, and it remains in this revised rule. Except for deletion of references to suspension of licenses which are covered by § 2.10, paragraph (c) remains as initially proposed.

We received 7 comments from the general public stating that the proposed regulations concerning denial and revocation of licenses are too lenient on facilities and on individuals and should be more stringent. We have attempted to strengthen the regulations in areas we believe will enhance our enforcement efforts. We believe that the regulations as proposed and as revised in this rule provide sufficient bases upon which to deny, suspend, or revoke licenses, and will assist us in handling noncompliance and other problematic situations we have encountered in regulating licensees.

Except for the changes described above, Subpart A—Licensing remains in the revised rule as originally proposed.

Subpart B—Registration

Proposed § 2.28, "Annual report of research facilities," is redesignated § 2.31 in this revised rule. Comments received addressing proposed § 2.28 are discussed under the heading, "Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities," subheading, "Proposed § 2.28 Annual report of research facilities."

Section 2.25 Requirements and procedures

We received 299 comments (274 from the research community and 25 from members of the general public) stating that § 2.25 as proposed is generally acceptable. Commenters who addressed the proposed registration requirements and procedures were concerned with the requirement that registrants update their registration form every 3 years. As explained in the supplementary information to the proposed rule, this requirement is new to the Animal Welfare regulations. We received 122 comments from the research community and l from a member of the general public stating that renewal of registration should be required every 5 years to coincide with the U.S. Public Health Service current requirement for the submission of assurance statements under the Health Research Extension Act of 1985. Five commenters from the research community stated more generally that the proposed requirements should coincide with those of the PHS. The proposed 3-year time period corresponds with other federal recordkeeping requirements, most

notably the USDA records retention and disposition policy, making it the most practical interval for us to administer. The PHS requirement for submission of assurances *up to* every 5 years is not inconsistent with the 3-year period we proposed. We have consulted with representatives from HHS specifically on this point, and they have indicated their willingness to abide by the 3-year registration renewal period as proposed. Accordingly, we are retaining the requirement for renewal of registration every 3 years.

We received one comment from a member of the research community requesting clarification regarding the requirement for registration by federal research facilities. We received another comment from a member of the research community requesting clarification of proposed § 2.25, generally. In response to the first comment, we are clarifying the section to state that federal research facilities are not required to register with the Secretary under the regulations. In response to the second comment, we note that except for provisions requiring research facilities to update their registration every 3 years, § 2.25 as proposed is substantially the same as it has been since 1967. We have experienced few problems in applying its requirements since that time, and we do not believe clarification is necessary.

Except for the clarification regarding federal research facilities, no changes are made in § 2.25 in the revised rule.

Section 2.26 Acknowledgement of regulations and standards

Proposed § 2.26 provides as follows:

> A copy of the regulations and standards in this Subchapter will be supplied with each registration form. The registrant shall acknowledge receipt of such regulations and standards and agree to comply with them by signing a form provided for such purpose by Veterinary Services. Such form shall be filed with the Area Veterinarian in Charge.

We received 299 comments (274 from the research community and 25 from members of the general public) stating that this section as proposed is generally acceptable. One commenter stated that it should be deleted from the regulations. The required acknowledgement is necessary to ensure that registrants have knowledge of the regulations and standards with which they must comply. A similar provision is contained in Subpart A—"Licensing" for the same reason. We believe that the acknowledgement should remain in the regulations.

One commenter requested general publication and distribution of the Animal Welfare Manual and applicable Veterinary Services Memoranda. These are internal USDA, APHIS documents intended to assist APHIS inspectors. They do not contain "rules of general applicability" and accordingly, there is no need to publish them in the Federal Register as part of the regulations.

The proposed section is substantially the same as current § 2.26. It remains as proposed.

Section 2.27 Notification of change of operation

Proposed paragraph (a) of § 2.27 requires that:

> [a] registrant shall notify the Area Veterinarian in Charge by certified mail of any change in the name or address, or any change in the operations or business, which would affect its status as a research facility, exhibitor, carrier, or intermediate handler, within 10 days after making such change.

We received 422 comments (397 from the research community and 25 from members of the general public) objecting that proposed § 2.27(a) is too broad. We received 295 comments (270 from the research community and 25 from members of the general public) expressing concern that the supplementary information is inconsistent with the proposed regulation because it is broader than the proposed regulation. The supplementary information accompanying Subpart B "Registration" states that notification is required "of any change in address, operations or management." The commenters expressed concern that the preamble language would encompass personnel or management changes which do not affect the information required by the registration form. Another commenter was concerned that the preamble implied that failure to report minor management or operations changes would be a violation of the regulations, and that clarification to avoid difficulties in interpreting this requirement is necessary. We are in agreement with these comments and are adopting the clarification suggested by a commenter, to read as follows:

> A registrant shall notify the Area Veterinarian in Charge by certified mail of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, exhibitor, carrier, or intermediate handler, * * *.

This revision should clarify that notification is required for operational changes which affect this registrant's status as a registered entity, in addition to name and address changes. This requirement will assist us in keeping accurate records on current registrants, and avoid wasting Agency resources when a registrant has gone out of business or has changed its operations.

We received 302 comments (277 from the research community and 25 from members of the general public) stating that notification should be required within 30 days instead of the 10 days proposed. The 10-day period is in the current regulations and has been in the regulations since they were first issued. It has caused no problems or difficulties and is a sufficient amount of time within which affected facilities can report. We are therefore retaining it in the regulations.

Except for the change in paragraph (a) set forth above, § 2.27 remains in the revised rule as initially proposed.

Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities

Introduction

Proposed Subpart C elicited numerous and varied comments addressing the proper role, duties, and authority of Institutional Animal Care and Use Committees ("Committees") and research institutions in promoting animal welfare. Many of the commenters expressed particular concern that the proposed regulations placed responsibilities on the Committee and on the attending veterinarian (Subpart D) that they believed should lie with the institution. There was also concern that APHIS was improperly placing the Committee and the attending veterinarian in the position of whistleblower and enforcer of the Animal Welfare regulations.

Research facilities have been required, through their animal care committee and/or attending veterinarian, to provide guidelines and consultation to their research personnel regarding the use of pain relieving drugs since the regulations were revised in accordance with the 1970 amendments to the Act. They have also been required to have a program of adequate veterinary care established and maintained under the supervision and guidance of a veterinarian. The 1985 amendments to the Act placed special significance on these institutional personnel as a means of assuring animal welfare, and represented a significant departure from the then-existing Act. The clear message from Congress was that additional regulatory efforts are needed to enhance animal welfare, to minimize animal pain and distress in research, and to restrict the multiple use of animals in major operative experiments. For the first time, Congress legislated that all research facilities must have an "Institutional Animal Committee" of a statutorily prescribed

composition with inspection and reporting duties (7 U.S.C. 2143(b)). Similar committees are already in place at research facilities receiving grant monies and awards from the U.S. Public Health Service under the Health Research Extension Act of 1985, Pub. L. 99–158, for research, training, and biological testing activities involving animals. Congress also mandated in the 1985 amendments to the Act that research facilities provide training to scientists, animal technicians, and other personnel involved with animal care and treatment. The Act retained the requirement that the facilities provide assurances they are adhering to the standards promulgated under the Act, and requires that they provide an explanation for any deviation from those standards. The 1985 amendments to the Act continue the Secretary's authority "to promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of this Act." (7 U.S.C. 2151).

The legislative history of the 1985 amendments to the Act demonstrates that at least one significant proponent in the Senate was of the view that "[v]eterinary inspectors from the U.S. Department of Agriculture cannot be present on a daily basis. However, their enforcement capability can and should be enhanced by the Institutional Animal Committee * * *." Senate Majority Leader Dole's statement, *Congressional Record*, December 18, 1985, at p. S17943.

As part of our response to the mandate from Congress, we proposed three new sections, §§ 2.30, 2.35, and 2.40, to implement the 1985 amendments to the Act. Section 2.30 sets forth responsibilities and requirements specifically imposed upon research facilities. Section 2.35 details the responsibilities and duties of the Institutional Animal Care and Use Committee which each research facility must establish. Section 2.40 details the requirement imposed upon all registrants and licensees to provide and maintain a program of adequate veterinary care and the requirements imposed upon attending veterinarians. This section consolidates the veterinary care regulations currently contained in each subpart of Part 3 and imposes additional requirements based upon the 1985 amendments to the Act.

Reorganization of §§ 2.30 and 2.35

Many comments we received were critical of the allocation of certain duties and responsibilities to the Committee and attending veterinarian rather than to the facility. Most of the comments we received were from members of the research community, the group most affected by the regulations proposed in Subpart C. Unless otherwise indicated, the comments addressed below were received from members of the research community.

Sixty-one commenters stated that too much authority would be given to the attending veterinarian and the Committee under the proposed regulations. We also received 400 comments (375 from the research community and 25 from members of the general public) objecting that the proposed regulations would place too much responsibility on the attending veterinarian and the Committee. Particular duties and areas of responsibility proposed in the regulations were singled out by the commenters as being improper and inappropriate.

The statutory language and the legislative history of the 1985 amendments to the Act support our proposal to impose various duties and responsibilities on the Committee and on the attending veterinarian. We agree, however, with the commenters that the ultimate responsibility for animal welfare at research facilities rests with the institutions themselves. We have carefully considered the comments we received, and have determined to reorganize and restructure portions of Subpart C in this revised rule to place responsibility on the research facilities, except where it is expressly reserved by the Act to the Committee. Similarly, we have revised portions of Subpart D concerning the requirement for a program of adequate veterinary care at research facilities to reflect that many of its aspects are the responsibility of the research facility, unless otherwise required by the Act.

Those areas of responsibility that are reassigned to the research facilities in the revised rule are described below under subject headings for ease of reference. We address the comments we received concerning the substance of the proposed provisions, as opposed to the allocation of responsibility for them, following this discussion.

The following chart provides the derivation of the paragraphs contained in § 2.30 in the final rule, as an additional aid to the reader. The paragraphs listed under the heading, "Revised rule" were derived from the corresponding paragraphs listed under the heading, "Proposed rule."

DERIVATION TABLE

Revised rule	Proposed rule
§ 2.30(a)	§ 2.30(a)
§ 2.30(b)	§ 2.30(b)
§ 2.30(c)	§ 2.30(c)
§ 2.30(d)	§ 2.30(d)
§ 2.30(e)(1)	§ 2.35(b)(3)(v)(A), (B)
§ 2.30(e)(2)	§§ 2.30(e)(1) and 2.35(b)(3)(vi)(A)
§ 2.30(e)(3)	§§ 2.30(e)(2) and 2.35(b)(3)(iv)
§ 2.30(e)(4)	§§ 2.35(b)(3)(iv), (vi)(F)
§ 2.30(e)(5)	§ 2.35(b)(3)(vi)(B)
§ 2.30(e)(6)	§§ 2.30(e)(3) and 2.35(b)(3)(vi)(C)
§ 2.30(e)(7)	§§ 2.30(e)(3) and 2.35(b)(3)(vi)(D)
§ 2.30(e)(8)	§ 2.30(b)(3)(vi)(D)
§ 2.30(e)(9)	§§ 2.30(e)(4) and 2.35(b)(3)(vi)(E)
§ 2.30(e)(10)	§ 2.30(e)
§ 2.30(f)	§§ 2.30(f) and 2.35(b)(3)(vii)(A)–(G)
§ 2.30(g)	§§ 2.30(g) and 2.35(c)
§ 2.30(h)	§ 2.35(d)
§ 2.30(i)	§ 2.35(f)
§ 2.30(j)	§ 2.35(b)(2)(iii)
§ 2.30(k)	§ 2.35(e)
§ 2.30(l)	§ 2.35(b)(3)(i)
§ 2.30(m)	§§ 2.35(b)(2)(i), (iv)

1. *Training.* Section 13(d) of the Act requires the research facility to train personnel involved with animal care and treatment (7 U.S.C. 2143(d)). We had proposed in § 2.35(f) that each research facility provide training for personnel in animal use, care, and treatment and that this training be provided through the Committee and the attending veterinarian. The Committee would review the training and designate those personnel requiring additional training, and the training program would include instruction in certain prescribed areas as well as in other areas the Committee may feel is necessary. We received 487 comments (462 from the research community and 25 from members of the general public) stating that these training requirements should not be included in § 2.35 since they are the facility's responsibility, not the Committee's. We agree that training is ultimately the responsibility of the facility. The Act does not reserve the training requirement to the Committee. Accordingly, in the revised rule we have removed training from § 2.35 and have included it in § 2.30(i) as a requirement for research facilities.

2. *Procedures for personnel to report violations.* Thirty-two commenters from the research community objected to the requirement contained in proposed § 2.35(b)(2)(iii) that the Committee establish procedures for personnel to report violations of the regulations or standards, including problems, deviations, or deficiencies with animal housing, care, or use. As proposed, the

Committee would also review and investigate reports, if warranted, and file a report. The commenters stated that the duty to establish these procedures should be imposed upon the research institution, and not the Committee. We agree that this requirement is not imposed upon the Committee by the Act and we therefore are including it in § 2.30(j) of the revised rule as the facility's responsibility. We continue to believe, however, that the Committee is the appropriate body to review and investigate any reports received because it is established to assess animal care and use and because it has inspection authority under the Act and the regulations. We are retaining that allocation of authority as proposed. The report prepared as a result of the Committee's review would be filed at the same central location as those prepared as part of the Committee's semiannual inspections.

3. *Response to Agency requests for information.* We received two comments objecting to proposed § 2.35(b)(3)(i) which would require the Committee to respond to requests from the Deputy Administrator [Administrator] to make research protocols [ACUPs] involving animals and assurance statements available to the Agency. The commenters stated that this should be the responsibility of the research facility, not the Committee. We agree that the research facility is ultimately accountable for responding to official Department requests, and we are including responsibility for doing so in § 2.30(l) of the revised rule as an additional requirement for research facilities. As explained in the revised rule for Part 1 published elsewhere in this issue, research protocol is changed to ACUP and Deputy Administrator is changed to Administrator. (*See* companion docket no. 88–013.)

4. *Use of pain relieving drugs.* Similarly, although we did not receive any comments regarding proposed § 2.35(b)(3)(iv), which requires the Committee to ensure that pain relieving drugs are used whenever an animal is involved in a painful procedure, the ultimate responsibility for this assurance lies with the facility and we are therefore including this requirement in § 2.30(e) in the revised rule.

5. *Painful procedures.* Ninety-four commenters from the research community objected to Committee responsibility for requiring certain assurances and conduct when painful procedures will be performed, as proposed in § 2.35(b)(3)(v) through (vii). Paragraph (v) of proposed § 2.35(b)(3) provides that the Committee shall require written assurances from the principal investigator that alternative procedures were considered for a procedure likely to cause pain or distress, that there are no other suitable procedures, and that the experiment is not unnecessarily duplicative. Paragraph (vi) of proposed § 2.35(b)(3) provides that the Committee must require that certain conditions are followed in any practice which could be expected to cause pain to animals. Paragraph (vii) of proposed § 2.35(b)(3) would require the Committee to asssure that no animal is used in more than one major operative experiment from which it is allowed to recover, except in certain circumstances. Again, research facilities are ultimately responsible for these assurances and for compliance with the requirements set forth in § 2.35(b)(3)(v) through (vii) as part of its operations. Because the Act does not specifically impose these duties on the Committee, we are placing them in paragraphs (e) and (f) of § 2.30 in the revised rule, as additional requirements for research facilities.

6. *Exceptions.* We did not receive any comments specifically addressing proposed § 2.35(c), which provides that exceptions to compliance with the Animal Welfare regulations and standards shall be made by the Committee only when necessary for the research design and they are specified in the protocol [ACUP]. A similar provision is contained in proposed § 2.30(g) with regard to painful procedures and major operative experiments from which an animal is allowed to recover. Under both sections, the principal investigator would be required to file a report with the Committee explaining any areas of noncompliance. A copy of the report must be kept on file by the facility and made available for Agency inspection or to officials of granting agencies. These provisions are set out in paragraphs (f) and (g) of § 2.30 in the revised rule, as the research facility is ultimately responsible for any exceptions to the Act and regulations, although exceptions must be approved by the Committee.

7. *Written procedures for exercise for dogs and for the psychological well-being of nonhuman primates.* We received 301 comments (276 from the research community and 25 from members of the general public) stating that the responsibility for carrying out the requirements of proposed § 2.35(d) should be imposed on the research facilities, and not the Committee. Thirty-five commenters similarly stated that the responsibility should be imposed on the research facility, which can then delegate authority to the Committee to carry out the requirements.

Proposed § 2.35(d) provides as follows:

> The Committee shall establish, in consultation with the attending veterinarian, written procedures and systems for the exercise of dogs and for the psychological well-being of primates in accordance with the regulations and standards, and a record system indicating that such a procedure or system is being carried out.

Again, the Committee is not required by the Act to establish these procedures, although it is required to inspect for compliance with the Act. Therefore, we are including the substance of proposed § 2.35(d) in § 2.30(h) as a requirement for research facilities in the revised rule.

8. *Federal research facilities.* The requirements contained in proposed § 2.35(e) "Federal research facilities," have also been moved to § 2.30 in the revised rule since they are a responsibility of a research facility, albeit a federal research facility, and not the Committee.

9. *Proposed* § 2.35(g) "Annual report of research facility" requires the Committee Chairman to sign an assurance statement on the Annual Report (VS Form 18–23) certifying that the Committee has carried out the responsibilities and requirements of § 2.35, that the facility is in compliance with the Animal Welfare standards, that the Committee has required a detailed explanation to be provided by the principal investigator when pain relieving drugs are withheld, that all explanations are attached to the annual report, and that the Committee has required that all other exceptions to the standards be required by research protocol [ACUP] and approved by the Committee. We received 49 comments stating that the responsible institutional official with authority to bind the facility should be required to sign the statement, not the Committee Chairman, since the provision of an adequate animal care and use program is the facility's responsibility. Twenty-nine commenters cited the assurance required in § 2.28(b)(9),"Annual report of research facilities," and objected that the additional assurance of the Committee Chairman required in proposed § 2.35(g) is redundant and outside the authority of the Act.

As discussed under the heading "Subpart B—Registration," in this final rule, only the responsible institutional official with authority to bind the facility will be required to sign the annual report. That official may in turn require assurances from the Committee of the kind proposed in § 2.35(g), however, we

are not requiring them in the facility's annual report The substance of the assurances that were required of the Committee Chairman in proposed § 2.35(g) will be deleted from that section and required instead in § 2.35(b)(2)(D) of the revised rule, as part of the Committee's report.

Subpart C of the revised rule has been rewritten to reflect that the areas of responsibility described above have been reassigned and are part of the requirements imposed upon research facilities. Comments we received addressing the substance of the proposed provisions of Subpart C, as opposed to comments addressing responsibility for those areas, are discussed below in the order in which those provisions appear in the revised rule. We believe that discussing the comments in this manner will help guide the reader through the substance of the revised rule.

General

We received 301 comments (276 from the research community and 25 from members of the general public) stating that this subpart should include standards which apply only to research facilities. Subpart C as proposed does apply only to research facilities and we do not find any ambiguity in either the heading or in the requirements themselves to cause the commenters to believe otherwise. We received 28 comments from the research community suggesting that we revise or delete the portions of Subpart C which address the formation and regulation of Institutional Animal Care and Use Committees. We partially agree with this comment and, as explained above, have revised §§ 2.30 and 2.35 which comprise Subpart C to reallocate authority and duties between the institution and the Committee so that the Committee will have only those specifically imposed upon it by the Act.

Seventy commenters suggested that the term "protocol" which appears in this section be changed to conform with the U. S. Public Health Service terminology which refers to "animal use procedure." As stated in the supplementary information accompanying the revised rule for Part 1—"Definition of Terms," published elsewhere in this issue (*see* companion docket no. 88–013), under the heading, "Protocol," the term "protocol" is changed to "animal care and use procedure" and is referred to in this document as the ACUP. The comments we received refer to "research protocols" as that term was used in the proposed rule. The term "research protocol" is used in this document when it is necessary to understand the substance of the comment. In those instances, ACUP appears in brackets following the term. In all other instances, we refer to the animal care and use procedure (ACUP).

Certain of the requirements pertaining to research facilities contained in §§ 2.30, 2.35, and 2.40 require that written policies and procedures be established. These include a written policy for any practice which might reasonably be expected to cause pain to an animal (proposed § 2.30(e)), written procedures and systems for the exercise of dogs and for the psychological well-being of nonhuman primates (proposed § 2.35(d)), and a written program of adequate veterinary care (proposed § 2.40(c)). (The requirement for a written program of adequate veterinary care applies to dealers and licensees, as well as to research facilities.) Research facilities that utilize written standard operating procedures (SOP) may satisfy these requirements by including the written policies and procedures in their SOPs.

Section 2.30 Additional requirements for research facilities

Section 2.30(a). Thirty commenters suggested that paragraph (a) of § 2.30 should specifically reference research facilities using or holding animals for experimentation, in addition to those using or holding animals for "research, testing, or teaching" as proposed. We did not propose to include separately "experimentation" since it is generally considered to be covered by the term "research." Section 2 of the Act defines "research facility" as one which, among other things, uses live animals in "research, tests, or experiments * * *" (7 U.S.C. 2132). Since the Act enumerates these functions, we agree that the regulations should as well. Section 2.30(a) is therefore revised by adding "experimentation" following "research."

We received 131 comments objecting to the requirement contained in proposed § 2.30(a)(2) that research facilities ensure that adequate veterinary care, including the appropriate use of drugs or euthanasia, is provided for at all times. We disagree with these commenters. We believe this requirement is necessary in order to fulfill the requirement of the Act that adequate veterinary care be provided at all times by research facilities (7 U.S.C. 2143(a)(3)(A). Section 2.30(a)(2) remains in the revised rule as initially proposed.

The requirements for adequate veterinary care are provided in Subpart D–"Attending Veterinarian and Adequate Veterinary Care." We are also adding a new paragraph (a)(3) to § 2.30 to state that research facilities are required to establish and maintain a written program of adequate veterinary care, in accordance with § 2.40. Proposed paragraph (a)(3) is redesignated (a)(4) in the revised rule.

Section 2.30(b). We received 322 comments (297 from the research community and 25 from members of the general public) stating that the Institutional Animal Care and Use Committee which § 2.30(b) requires to be established and maintained should be renamed the "Institutional Animal Committee" to be consistent with the Act. For the reasons explained under the heading, "Committee," in the supplementary information to the revised rule for Part 1—"Definition of Terms," published elsewhere in this issue of the **Federal Register** (*see* companion docket no. 88–013), we have determined that "Institutional Animal Care and Use Committee" is more appropriate since it is descriptive of the areas of concern to the Committee and is consistent with the terminology used by the Public Health Service, National Institutes of Health, which utilizes similar committees. No change is made to the name of the Committee in the revised rule.

Section 2.30(c). As proposed, § 2.30(c) would require research facilities to "provide the Committee and the attending veterinarian with the authority to enter all animal areas at any reasonable time in order to carry out their responsibilities." We received 535 comments (510 from the research community and 25 from members of the general public) objecting to this requirement on the grounds that it exceeds our statutory authority, could interfere with research, and could lead to unauthorized release of proprietary information. We believe these concerns are unwarranted.

First, statutory authority exists: the Act directs the Secretary to promulgate standards with respect to animals in research facilities, to include requirements for animal care, treatment, and practices to ensure pain and distress are minimized, for adequate veterinary care with appropriate use of drugs, for consideration of alternatives to any painful procedure, for consultation with a doctor of veterinary medicine in the planning of painful procedures, and for ensuring that an animal is not used in more than one major operative experiment from which it is allowed to recover except if scientifically necessary (7 U.S.C. 2143(a)(3)). The Act specifically authorizes the Committee, of which the

attending veterinarian is a member, to conduct inspections of research facilities, to review practices involving animals and the condition of animals, and to ensure compliance with the provisions of the Act to minimize pain and distress to animals (7 U.S.C. 2143(b)(3)). Section 21 of the Act authorizes the Secretary to "promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of [the] Act." (7 U.S.C. 2151).

Second, concerns that inspections at any time could interfere with ongoing research and with research results by disturbing the animals or upsetting the controlled environment could be allayed by providing guidelines for conducting inspections in the facility's written policies and procedures. In this manner, facility personnel, including Committee members and the attending veterinarian, will be informed of any necessary and reasonable restrictions on the timing of inspections before any are performed under these regulations. The establishment of guidelines would help reassure research personnel that the inspection regulations are implemented in good faith. We caution, however, that they must not be used as a means of preventing inspections during research, surgery, or other procedures.

Third, regarding release of trade secret or proprietary information, the scientific or proprietary portion of ongoing research is not the subject of inspection. Moreover, even if trade secrets or proprietary information were apparent on physical inspection, Section 27 of the Act makes it unlawful for any member of the Committee to release any confidential information of the research facility, including trade secrets, and provides sanctions for violations (7 U.S.C. 2157). This statutory deterrent should alleviate concerns about the unauthorized release of proprietary information.

It is necessary that the Committee be assured free access to all animal areas to perform its responsibilities and duties properly. Access to all animal areas at any reasonable time to conduct inspections as the Committee deems appropriate must be assured in order to effectuate the purposes of the Act and as a means of promoting compliance with the Act and the regulations between Committee inspections. Reports are not a substitute for first-hand observation of animal care to ensure compliance.

We are revising § 2.30(c) in the revised rule to require that each research facility must also provide the attending veterinarian with the authority to enter all animal areas at any time, to ensure compliance with the facility's program of adequate care. As explained in greater detail below under the heading, "Subpart D—Attending Veterinarian and Adequate Veterinary Care," this access is necessary to enable attending veterinarians to perform their duties as intended by the Act. Section 2.30(c) is revised to reflect this change.

Section 2.30(d). Proposed § 2.30(d) would require Committee approval only for research protocols [ACUPs] falling under Categories 3 and 4 of the "Categories of Animal Use in Research and Teaching" in proposed § 2.35(b)(3)(ii). which categorize procedures according to the degree of animal pain or distress involved. Procedures that involve "significant but unavoidable pain or distress to the animals" are in Category 3. Procedures that involve "the inflicting of severe pain or distress or chronic, unrelieved pain or distress, or death" are in Category 4. Procedures that involve no pain or minor pain are in Category 1 and 2, respectively.

Nineteen commenters (16 from the general public and 3 from the research community) suggested that the Committee review and approve all research protocols [ACUPs] instead of only those classified in the third and fourth categories of pain. One commenter suggested that the Categories of Animal Use could result in researchers classifying their procedures in Categories 1 and 2 to avoid closer scrutiny.

We initially proposed Committee review of protocols [ACUPs] involving more significant amounts of pain or distress as a means of fulfilling the intent of Congress to minimize animal pain and distress. The Committee would approve of those ACUPs only if they were shown to be justified and scientifically necessary and if alternatives were considered and determined to be unsatisfactory. Closer scrutiny of procedures falling in Categories 3 and 4 was considered appropriate to focus attention on these concerns.

Upon reconsideration of the utility of the "Categories of Animal Use" and the difficulty of designing or selecting a practical and appropriate categorization system, we have decided to adopt the suggestion of these commenters and require approval of all ACUPs by the Committee. This practice is currently required by the U.S. Public Health Service (PHS) and therefore all research facilities receiving grants or awards under the Health Research Extension Act of 1985, Pub. L. 99–158, are already doing so. Accordingly, this requirement should not be a burdensome addition to the requirements already imposed upon research facilities.

For these reasons and as more fully explained below in the discussion of comments addressing proposed § 2.35, we are eliminating the "Categories of Animal Use in Research and Teaching" from the regulations.

We understand that the requirement for Committee review and approval of all ACUPs will impose a greater burden on the Committee's human resources and we have therefore provided a mechanism to enable the Committee to accomplish its tasks. As is more fully explained below in the discussion of § 2.35, approval by a quorum of the Committee will be required for all ACUPs. However, the Committee can assign individual members to review designated ACUPs and to present them to the Committee for approval or disapproval. In this manner, the Committee should not become overburdened or a bottleneck in the research approval process.

We received 596 comments (571 from the research community and 25 from members of the general public) stating that the requirement in proposed § 2.30(d) that the Committee review research protocols [ACUPs] exceeds our statutory authority. We received 382 comments (357 from the research community and 25 from members of the general public) stating that the requirement for protocol [ACUP] review by the Committee should be deleted. The Act provides ample authority for requiring Committee review of "protocols" [ACUPs] and that Committee review is necessary to fulfill the intent of Congress.

Section 13 of the Act (7 U.S.C. 2143) directs the Secretary to promulgate standards to govern the humane handling, care, treatment, and transportation of animals by research facilities and other regulated entities. In addition to the requirements for exercise of dogs and for a physical environment adequate to promote the psychological well-being of nonhuman primates, the Secretary is directed to include requirements for animal care, treatment, and practices in experimental procedures to minimize animal pain and distress; for requiring the principal investigator to consider alternatives to any painful procedure; for requiring consultation with a doctor of veterinary medicine; for use of pain relieving drugs; for pre- and post-surgical care by laboratory workers; and for ensuring that no animal is used in more than one major operative experiment from which it is allowed to recover except in certain circumstances. The Act states that

exception to these standards may be made "only when specified by research protocol and that any such exception shall be detailed and explained in a report outlined under paragraph (7) and filed with the Institutional Animal Committee." (7 U.S.G. 2143(a)(3)(E)).

Paragraph (7) of Section 13 of the Act (7 U.S.C. 2143(a)(7)) directs the Secretary to require each research facility to show upon inspection and through reports that it is complying with the Act and that professionally acceptable standards of care are being followed. In order to do so, each facility must provide information on painful procedures used, assurances that alternatives were considered, assurances that the facility is adhering to the regulations promulgated under section 13 of the Act, and an explanation for any deviation from those regulations (7 U.S.C. 2143(a)(7)).

The Secretary is directed by the Act to require the establishment of a Committee at every research facility, in order to assess animal care, treatment, and practices (7 U.S.C. 2143(b)(1)). The Committee is statutorily directed to:

> Inspect at least semiannually all animal study areas and animal facilities of such research facility and review as part of the inspection—(A) practices involving pain to animals, and (B) the condition of animals to ensure compliance with the provisions of [the] Act to minimize pain and distress to animals. (7 U.S.C. 2143(b)(3)).

The Committee is also directed to file an inspection certification report which includes:

> Reports of any violation of the standards promulgated, or assurances required, by the Secretary, including any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any corrections made thereafter; * * * (7 U.S.C. 2143(b)(4)).

In order for research facilities to provide the assurances required, they must be cognizant of all procedures at the facility involving animals and they must make a determination that the procedures are in compliance with the Act and the regulations. This can best be accomplished through the Committee. Research facilities will necessarily rely upon Committee inspection reports in order for them to provide the assurances required in their annual report in good faith. The responsible institutional official with authority to bind the facility will need to rely upon the Committee's reports in certifying compliance with the Act and the regulations, as required in § 2.31 of the final rule. Without this mechanism, the assurances and certifications might be successfully challenged as not based on actual knowledge.

We have determined that it is necessary that the Committee review all ACUPs, referred to as "research protocols" in our proposed regulations, in order to fulfill the intent of the Act and to effectuate the express purposes of the Act.

We received 120 comments stating that review of protocols [ACUPs] should be limited to conform with the U.S. Public Health Service policy which requires Committee review of only those components of research protocols related to animal care and use. We believe that much of the resistance to the proposed requirement that the Committee review "research protocols" arises out of a misconception that the Committee would be involved in evaluating the design, outlines, guidelines, and scientific merit of proposed research. As stated in the supplementary information accompanying the revised rule for Part 1—"Definition of Terms," published elsewhere in this issue (*see* companion docket no. 88–013), this is not the case. The Committee will be involved with reviewing how the research will treat or affect an animal, the condition of an animal, and the circumstances under which an animal will be maintained. It will not be involved in evaluating the design, outlines, guidelines, and scientific merit of proposed research. The requirement that the Committee review what is now termed the ACUP remains in this revised rule as proposed, except that the Committee will review all ACUPs, and not just those involving significant or severe degrees of pain or distress.

Two commenters (1 from the general public and 1 from the research community) wanted Committee meetings and ACUP review to be open to the public. There is nothing in the Act which either requires or prohibits conducting Committee business in public. Local sunshine laws may require state agencies to conduct open meetings. Otherwise, the decision whether to do so is left to the research facilities. It will not be addressed in the regulations.

In considering the provisions of proposed § 2.30(d), 2 commenters stated that regulations should be formulated to protect research facilities' trade secrets. The 1985 amendments to the Act added section 27, which declares it unlawful for any member of a Committee to release any confidential information of the research facility, including any which concerns or relates to trade secrets (7 U.S.C. 2157). Section 27 also specifies the punishment for a violation and clearly provides that any injured person has a private cause of action. It is our belief that this statute and other laws regarding trade secrets provide sufficient protection and that the promulgation of regulations is not needed.

Two commenters stated that, under proposed § 2.30(d), the Committee should review and approve not just painful procedures, but also the species of animals to be used for proposed research, the number to be used, the type of housing to be used, any experimental methods to be employed, and the training of investigators. As stated above, we proposed the requirement for review of the procedures classified in Categories 3 and 4 because the stated intent of Congress in amending the Act was to minimize animal pain and distress, multiple major surgeries, and unnecessary duplication of animal research. The Committee is required and authorized to assess animal care, treatment, and practices in experimental research. There is no indication in the Act or in the the legislative history of the Act that Congress intended the Committee to consider the species and number of animals used, the housing to be used, experimental methods, or training of investigators, other than as they affect animal care, treatment, and procedures. Requirements for training are imposed by the Act upon the facilities (7 U.S.C. 2143(d)). All exceptions to the regulations and standards must be explained and justified by the ACUP and approved by the Committee. Accordingly, we do not agree that additional reference to Committee review of these areas is needed.

Except for the change explained above to require review of all ACUPs by the Committee, § 2.30(d) remains in the revised rule as originally proposed.

Section 2.30(e). As described above, areas of responsibility have been reassigned from the Committee to the research facility and accordingly are added to § 2.30. Comments concerning the substance of those provisions will now be addressed in the order in which they appear in the revised rule, beginning with § 2.30(e). We will discuss the material under subject headings. The section designations used in the proposed rule have been changed and are not used. However, we have included the former section designations as they appeared in the proposed rule so that the reader can cross-reference the proposal.

Painful procedures. In enacting the 1985 amendments to the Act, Congress

was particularly and expressly concerned with minimizing animal pain and distress. Toward this end, proposed § 2.30(e) would require research facilities to establish a written policy applicable to any practice which may be painful to an animal. The policy must require various measures to be taken when painful procedures are performed and must be designed to ensure that these measures are adequately followed. Proposed § 2.35 contains similar requirements although it places the responsibility for ensuring compliance with those measures on the Committee. As fully explained above under the heading, "Reorganization of §§ 2.30 and 2.35," we are in agreement with the comments which suggested that responsibility for these matters belongs to the research facilities and not the Committee, and we have revised § 2.30(e) to reflect this reallocation of responsibility.

Section 2.30(e) applies to all painful procedures and to those that might reasonably be expected to be painful. The use of pain relieving drugs, anesthetics, analgesics, and tranquilizers does not mean that a procedure is not painful. This section applies to all procedures that involve pain or that might be expected to involve pain, whether or not the pain is relieved.

Each paragraph of § 2.30(e) is discussed individually below in numbered sections because the section is rather lengthy. Each discussion begins with the requirement of the revised rule and then explains its derivation from the proposal. Comments concerning the different provisions are then addressed. We believe this approach will assist the reader in understanding the requirements and rationale of this revised rule.

1. Section 2.30(e)(1) of the revised rule directs the research facility to require written assurance from the principal investigator to the Committee that alternative procedures were considered but were not suitable, and that the experiment does not unnecesssarily duplicate previous experiments. The assurance must be given before a painful procedure can be undertaken. The assurance must also indicate what information sources were consulted, what alternative procedures were considered, and what techniques are planned to minimize pain and discomfort to the animals. This requirement was originally imposed upon the Committee in proposed § 2.35(b)(3)(v) and on the research facility in proposed § 2.30(d).

We received a number of comments concerning this assurance. We received 402 comments (377 from the research community and 25 from members of the general public) objecting to the assurance required of the principal investigator as either duplicative or not authorized by the statute. We have, by reorganizing §§ 2.30 and 2.35, eliminated duplicative assurances. In the revised rule, the assurance is only required of the research facility. The assurance is not only authorized by the statute, but is in fact mandated by it. Section 13(a)(3)(B) of the Act requires that the principal investigator consider alternatives to painful procedures and section 13(a)(7)(B)(i) of the Act requires research facilities to provide an assurance demonstrating that this has been done (7 U S.C. 2143(a)). The assurance is therefore necessary to enable the research facility to comply with the Act.

We received 138 comments (136 from members of the general public and 2 from the research community) expressing their belief that there is a need for greater proof that alternative methods were sought or considered and that the experiment is not unnecessarily duplicative. One member of the general public commented that the requirement for an assurance that a painful procedure is not unnecessarily duplicative needs clarification.

Our consultation with HHS included consideration of this provision. Representatives from HHS were concerned that the phrase "unnecessarily duplicat[ive]" could be misconstrued. They pointed out that intentional replication of research is often an essential component of research, either for validation of the findings of others or to establish an in-house model of research that was developed elsewhere. They also pointed out that section 13(e) of the Act requires the Secretary to establish an information service at the National Agricultural Library to provide information which "could prevent unintended duplication of animal experimentation * * *" (7 U.S.C. 2143(e)). Section 1(b)(3) of the Act, however, includes a finding of the Congress that "measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds; * * *" (7 U.S.C. 2131(b)(3)). Deliberate duplication of research can be deemed necessary if approved by the Committee. We do not agree that additional clarification of the regulation is needed.

Eight commenters suggested rewording the assurance required in proposed § 2.35(b)(3)(v)(B) from "[T]he assurance is to indicate what information sources were consulted, * * *" to "[t]he assurance is to indicate to the satisfaction of the Committee * * *." For the following reasons, we do not agree that this change is necessary. The requirements of § 2.30, including the requirement that the Committee approve the ACUP, must be satisfied before a painful procedure can commence. Sections 2.30(d) and (e) of the final rule require the principal investigator to provide a written statement to the Committee stating that alternative procedures were considered and that the procedure is not unnecessarily duplicative, as part of the Committee's ACUP review and approval process. The ACUP would not be approved by the Committee unless it is satisfied with the assurance. Moreover, it is the responsibility of the research facility to require this assurance and they in turn must certify that they have in fact done so as part of their annual report. These provisions taken together should be sufficient to prevent unnecessary duplication of research.

2. Section 2.30(e)(2) of the revised rule provides that the research facility must require the principal investigator to consult with the attending veterinarian in the planning of a painful procedure, and that the principal investigator must consult with the attending veterinarian during the procedure under certain circumstances. The attending veterinarian must be allowed to observe the procedure at any time to ensure compliance with the regulations. In proposed § 2.35(b)(3)(vi)(A), the Committee was directed to require the principal investigator to consult with the attending veterinarian. In proposed § 2.30(e)(1) the research facility was required to establish a written policy ensuring that this consultation is conducted.

We received 148 comments stating that the phrase "and during the procedure" should be deleted from proposed § 2.30(e)(1). The commenters expressed concern that consultation during the conduct of an approved procedure would be prohibitively costly and would place the attending veterinarian in the position of policing the institution for compliance with the Animal Welfare regulations. We had intended that the attending veterinarian must be readily available during the course of a painful procedure to consult in the event of special, unanticipated, or unusual situations, and have therefore rephrased the requirement in the revised rule to make clear our intent. We also believe that the attending veterinarian should be allowed to make random checks of procedures to assure that the

regulations and standards are being followed. We have found that on occasion the attending veterinarian has become aware of a noncompliance situation in a classroom or laboratory and has been prevented from remedying it. We have also learned of instances where the attending veterinarian has been prevented from entering an animal area once a procedure has begun. To ensure that these situations do not occur, and that the attending veterinarian is not obstructed in performing his or her duties, the attending veterinarian must have the authority to conduct random oversight inspections of procedures in progress. We have clarified § 2.30(e)(2) in the revised rule to reflect that the attending veterinarian must be available for consultation during a painful procedure as well as during ACUP planning and development. It also requires that the research facility ensure that the attending veterinarian is allowed access to all animal and research areas to observe the procedure at any time during the course of the procedure, in order to fulfill the requirements of paragraph (e)(2).

3. Section 2.30(e)(3) of the revised rule requires research facilities to require the use of pain relieving drugs, anesthetics, analgesics, and tranquilizers to minimize pain unless they are withheld in accordance with the provisions of § 2.30(e)(4), and that they be administered in accordance with the directions and recommendations of the attending veterinarian and in accordance with the accepted or established use of the drugs. Proposed § 2.35(b)(3)(iv) would have required the Committee to ensure that pain relieving drugs are used in any painful procedure unless an exemption is approved by the Committee and the attending veterinarian. Proposed § 2.30(e)(2) would have required the research facility to establish a written policy ensuring the proper use of pain relieving drugs. For the reasons stated above under the heading, "Reorganization of §§ 2.30 and 2.35," in this revised rule the research facility, not the Committee, is responsible for requiring that pain relieving drugs are used unless withholding them is scientifically necessary, fully explained and justified in the ACUP, and approved by the attending veterinarian and the Committee, in accordance with § 2.30(e)(4).

One commenter objected in general to the requirement that pain relieving drugs be used in any procedure that would reasonably be expected to cause pain or distress in a human subject. The commenter stated that this is not always consistent with current veterinary practice. We believe that the exemption provision in § 2.30(e)(4) adequately addresses those instances when use of pain relieving drugs is not consistent with current veterinary practice, and that the presumption should remain in favor of providing pain relieving drugs, in order to carry out the purposes of the 1985 amendments to the Act.

4. Section 2.30(e)(4) of the revised rule provides that research facilities must require that pain relieving drugs, anesthetics, analgesics, and tranquilizers be reduced in amount or withheld only if scientifically necesssary, fully explained in the ACUP, and approved by the attending veterinarian and the Committee. The drugs can then be reduced in amount or withheld only for as long as necessary, as specified in the ACUP. Proposed § 2.30(e)(2) would require each research facility to establish a written policy providing for the proper use of pain relieving drugs. Proposed § 2.35(b)(3)(iv) would place responsibility for ensuring the proper use of pain relieving drugs on the Committee and would provide that pain relieving drugs could only be minimized or withheld if fully explained and justified in the research protocol [ACUP] and agreed to by the Committee and the attending veterinarian. Proposed § 2.35(b)(3)(vi)(F) would place specific responsibility on the Committee for prohibiting the withholding of pain relieving drugs except when scientifically necessary and approved by the Committee and the attending veterinarian.

We received 138 comments (136 from members of the general public and 2 from the research community) stating that stronger regulations requiring pain relieving drug use are necessary. We disagree that stronger regulations are needed. Responsibility for requiring proper use of pain relieving drugs is placed on the research facility in this revised rule in response to the comments suggesting that the facility and not the Committee is ultimately responsible for this assurance. The responsible institutional official will be required to certify in the annual report that the research facility has complied with the regulations concerning use of pain relieving drugs. Accordingly, we believe that additional regulations are not necessary.

One commenter objected to the authority given to the attending veterinarian to overrule in effect the Committee's decision with regard to the grant or denial of an exemption from the requirement to use pain relieving drugs, since the Act only requires consultation. The Act requires that pain and distress be minimized or eliminated. We believe that the attending veterinarian, by virtue of his or her training, duties, and responsibility, is qualified to make this assessment on behalf of the animals. It is the responsibility of the principal investigator to convince the Committee and the attending veterinarian that scientific necessity justifies withholding drugs. If the Committee is convinced of the scientific necessity, it too can attempt to convince the attending veterinarian. We believe that full concurrence by the Committee and the attending veterinarian is necessary in this area, due to the stated intent of Congress.

5. Section 2.30(e)(5) of the final rule directs research facilities to require that the attending veterinarian provide training of laboratory personnel in the proper use of pain relieving drugs so as to minimize pain and distress to animals. Proposed § 2.35(b)(3)(vi)(B) would have required the Committee to require that the principal investigator provide for the proper use of pain relieving drugs in accordance with established or accepted veterinary procedures, and provide for training of laboratory personnel to carry out those procedures. We did not receive any comments addressing the substance of the requirement as proposed. However, as part of the reassignment of responsibilities and the reorganization of §§ 2.30 and 2.35, responsibility for training of laboratory personnel in those procedures is placed on the research facility in the revised rule.

We also believe that the attending veterinarian is in the best position and is most qualified to provide training of laboratory personnel in the proper use of pain relieving drugs because of his or her expertise in medicine and in established or accepted veterinary procedures. Accordingly, while research facilities are ultimately responsible for ensuring that this training is provided, we believe that it is most appropriately carried out through the attending veterinarian.

6. Section 2.30(e)(6) of the revised rule directs research facilities to require that all pre-procedural, procedural, and post-procedural care be provided by laboratory workers or surgical personnel, in accordance with the attending veterinarian's instructions and established veterinary medical and nursing procedures. It also directs research facilities to require that this care and the qualifications of those personnel be evaluated and approved by the attending veterinarian. Proposed

§ 2.30(e)(3) would have required each research facility to establish a written policy ensuring all pre-surgical, surgical, and post-surgical care by laboratory workers is in accordance with established veterinary medical and nursing procedures, and ensuring that the care, surgical rooms, and qualifications of surgical personnel have been evaluated and approved by the attending veterinarian. Proposed § 2.35(b)(3)(vi)(C) would have required the Committee to require that pre-surgical and post-surgical care be provided by laboratory workers, in accordance with the instructions of the attending veterinarian and established veterinary medical and nursing procedures. In the revised rule, this responsibility is placed on the research facility because, as discussed under the heading, "Reorganization of §§ 2.30 and 2.35," the facility is ultimately responsible for proper care.

Also, because the facility is responsible for the acts of its employees, it is ultimately responsible for ensuring their qualifications. Evaluation of the qualifications of personnel is carried out through the attending veterinarian because he or she is most qualified to evaluate those qualifications.

In the revised rule, the requirements imposed on the research facilities encompass pre-procedural, procedural, and post-procedural care, and are not limited to surgical procedures. This revision is necessary because painful procedures, as defined in the revised rule for Part 1 (*see* companion docket no. 88-013), published elsewhere in this issue, include any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied. Therefore, practices or procedures that might reasonably be expected to be painful procedures, are not limited to surgical procedures. The Act directs the Secretary to promulgate requirements "for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized, including adequate veterinary care * * *" (7 U.S.C. 2143(a)(3)(A)). All procedures must be covered by the required program of adequate veterinary care in accordance with the Act. Accordingly, it is necessary to direct that research facilities require that personnel rendering pre-procedural, procedural, and post-procedural care perform in accordance with the instructions of the attending veterinarian, and that the care and the qualifications of personnel be evaluated and approved by the attending veterinarian, in order to ensure adequate veterinary care and to effectuate the mandate of the Act.

Six commenters stated that the word "veterinary" preceding "medical and nursing procedures" should be deleted from proposed § 2.35(b)(3)(vi)(C). We believe that it is more precise to specify veterinary medical and nursing procedures when we are referring to care and procedures involving animals. Therefore, the word "veterinary" is retained in § 2.30(e)(6) in the revised rule.

7. Section 2.30(e)(7) of the revised rule provides that research facilities must require that all survival surgeries be conducted only in facilities intended for that purpose, that they be operated and maintained under aseptic conditions, and that surgical rooms be evaluated and approved by the attending veterinarian. Proposed § 2.30(e)(3) would have required each research facility to establish a written policy ensuring, among other things, that surgical rooms be evaluated and approved by the attending veterinarian. Proposed § 2.35(b)(3)(vi)(D) would have required the Committee to require that all aseptic survival surgeries be conducted in facilities intended for that purpose, that such facilities be operated and maintained under aseptic conditions, and that any surgery be performed or directly supervised by trained, experienced personnel. This responsibility has been placed on the research facility in the revised rule since the facility is ultimately responsible for the proper conduct of surgeries.

We received 12 comments suggesting that we restrict the requirements for "all aseptic survival surgeries" to non-rodent species. The regulations do not apply to laboratory bred rats and mice and therefore no such restriction is necessary.

We also received 387 comments (362 from the research community and 25 from members of the general public) objecting to the requirement that all aseptic survival surgeries be conducted in facilities intended for that purpose as too restrictive. One commenter suggested that we distinguish between major and minor surgical procedures. We disagree with these comments. The suggested major/minor distinction would likely lead to disputes over what should be considered major and what minor. By its terms, the requirements provided in § 2.30(e) are limited to painful procedures. We believe that this is the appropriate distinction upon which to base the requirements contained in paragraph (e)(7). We are therefore retaining the requirements stated above for all survival surgeries which are painful procedures.

8. Section 2.30(e)(8) of the revised rule provides that research facilities must require that any surgery be performed or directly supervised by trained, experienced personnel. Proposed § 2.35(b)(3)(vi)(D) would have required the Committee to require that all aseptic survival surgeries be performed or directly supervised by trained, experienced personnel. For the reasons provided under the heading, "Reorganization of §§ 2.30 and 2.35," and because responsibility for the proper conduct of surgical procedures ultimately belongs to the facility, this responsibility is placed on the research facility in the revised rule.

9. Section 2.30(e)(9) of the revised rule requires research facilities to prohibit the use of paralytic drugs without anesthesia. Proposed § 2.30(e)(4) would require each research facility to establish a written policy prohibiting the use of paralytic drugs without anesthesia and proposed § 2.35(b)(3)(vi)(E) would require the Committee to do so as well. For the reasons provided under the heading, "Reorganization of §§ 2.30 and 2.35," this responsibility is placed on the research facility in the revised rule, since it is ultimately responsible for rendering proper care.

Thirty-one commenters stated that "paralytic drug" should be defined in the regulations. We agree and are including a definition of "paralytic drug" in revised Part 1—"Definition of Terms," published elsewhere in this issue of the Federal Register (*See* companion docket no. 88-013.)

One commenter suggested strengthening the proposed regulations by stating the level of surgical anesthesia that should be required in order to use a paralytic drug. We believe that this is a matter that should be left to the research facility's program for providing adequate veterinary care. Also, consultation with the attending veterinarian should include matters such as the proper level of surgical anesthesia.

10. Section 2.30(e)(10) of the revised rule requires research facilities to establish a written policy to ensure compliance with the provisions of §§ 2.30(e) (1) though (9). Proposed § 2.30(e) would have required research facilities to establish a written policy limited to ensuring the various aspects of veterinary care and procedures provided in proposed § 2.30(e). Due to the reassignment of responsibilities in Subpart C, the written policy must be extended to cover additional areas of

animal care and treatment. For this reason, the requirement to establish a written policy is revised to cover the provisions of paragraphs (e) (1) through (9).

We received 123 comments stating that establishing a written policy for the veterinary consultation required by proposed § 2.30(e)(1) (§ 2.30(e)(2) in the revised rule) is unnecessary. Since facilities are responsible for requiring this consultation and for maintaining a program of adequate veterinary care, and must certify that the required care is being provided in accordance with the Animal Welfare regulations and standards, it is necessary that each research facility have a written policy so that the rules all personnel must follow are clear. The written policy must be provided to all principal investigators so that they can comply with its provisions. Distribution of the policy will ensure that all personnel have knowledge of the required consultations and procedures for minimizing and reducing animal pain, and can be held responsible by facilities for compliance with it. A written policy will also reduce any confusion over what is required before a painful procedure can be performed, and will standardize procedures within a research facility. Without a written policy the research facility would not be able to adequately monitor compliance by its personnel and could not assure that the requirements of the law were being followed. We have retained the requirement that a written policy be established requiring veterinary consultation and the other provisions of § 2.30(e) in this revised rule.

Section 2.30(f) Multiple major operative experiments. Section 2.30(f)(1) of the revised rule states that research facilities using or holding animals for research, testing, or teaching must establish and follow written procedures which assure that no animal is used in more than one major operative experiment from which it is allowed to recover except under the circumstances provided in the regulation. Proposed § 2.30(f) would have required research facilities to establish procedures which assure that no animal is used in more than one major operative experiment from which it is allowed to recover except as provided in proposed § 2.35. Proposed § 2.35(b)(3)(vii) would have required the Committee to assure that no animal is so used except in certain circumstances provided in proposed § 2.35(b)(3)(vii) (A) through (G) of the section. Because the research facility is ultimately responsible for assuring the proper use of animals, the requirements to assure that no animal is used in more than one major operative experiment from which it is allowed to recover except in certain circumstances and to establish procedures which assure this are placed on the facility. We are requiring, in this revised rule, that the procedures be in writing so that all personnel will have knowledge of them.

We received 39 comments objecting to the limitation on major operative experiments using the same animal. The commenters stated that this would interfere with research involving extensive behavior training or other research.

We understand that this requirement may interfere with some research which involves animals used in multiple surgeries which are unrelated, or which are not part of the same procedure, or which do not fall under any of the exceptions provided in the regulations. This is precisely what the Act intended. Section 13(a)(2)(D) of the Act requires the Secretary to promulgate standards including requirements that "no animal is used in more than one major operative experiment from which it is allowed to recover except in cases of—(i) scientific necessity; or (ii) other special circumstances as determined by the Secretary; * * *" (7 U.S.C. § 2143(a)(2)(D)). The regulations prevent multiple use of animals only when there is no scientific necessity or other special circumstances justifying it. The regulations include a mechanism for obtaining permission from the Secretary if special circumstances exist which are not included in the regulations. We believe that this regulation will not interfere with the justified use of an animal in multiple surgeries.

Four commenters from the general public stated that the regulation provides too many exceptions from the prohibition against multiple surgeries, and that the exceptions are too broad. One commenter stated that the terms "major operative experiment" and "scientific necessity" should be defined and that the exceptions should not apply to animals used in teaching and demonstration exercises. We believe that the exceptions provided in the regulation are all necessary exceptions to the prohibition of the Act. We also believe the exceptions are stated narrowly. The exception for scientific necessity requires approval by the Committee and is not subject to unilateral interpretation by the investigator. The Committee is the appropriate body to evaluate whether or not a proposed procedure is scientifically necessary, and we do not believe it is necessary to define this term. The term "major operative experiment" is defined in Part 1—"Definition of Terms." (*See* companion docket no. 88-013, published elsewhere in this issue.) Whether exceptions should be made for animals used in research, testing, teaching and demonstration exercises is left to the research facilities, however the exceptions granted must still fall within one of the circumstances provided in the regulation in order to use an animal in multiple major operative experiments. No changes have been made based upon this comment.

Section 2.30(g) Exceptions. Section 2.30(g) of the revised rule provides the limited circumstances under which exceptions to the Animal Welfare standards and regulations can be made. It also provides the reporting procedure which must be followed if an exception is made by a research facility.

Responsibility for granting exceptions is placed on the research facility in the revised rule, since it is the research facility's responsibility under the Act to certify compliance with the standards and regulations and to explain any deviation from the standards (7 U.S.C. 2143(a)(7)(B)). The Committee must first approve the ACUP since its duty is to assess animal care, treatment, and practices, and since the Act requires that any exceptions to the standards be made only when specified by research protocol and when detailed and explained in a report filed with the Committee (7 U.S.C. 2143(a)(3)(E)). The research facility can grant exceptions to the standards and regulations only when necessary for the accomplishment of the research design, and only if the exception: (1) Is specified in the ACUP; (2) is explained in detail; and (3) is approved by the Committee. The principal investigator must file a report with the Committee before it reviews the ACUP, detailing the areas of noncompliance. The facility must keep a copy of the report on file and make it available to APHIS inspectors and officials of funding Federal agencies. The facility must attach a copy of all reports detailing and explaining exceptions to compliance to its annual report.

As revised, § 2.30(g) consolidates the provisions of proposed §§ 2.30(g) and 2.35(c). Proposed § 2.30(g) would have allowed exceptions to the requirements of proposed § 2.30 (e) and (f) (animal care assurances and procedures assuring against multiple use of animals in major operative experiments, respectively) to be made only when specified by the "research protocol" [ACUP] and approved by the Committee. The principal investigator would be required to detail and explain

the exception in a written report to be filed with the Committee and attached to the facility's annual report to the Department. It would also provide for withholding of pain relieving drugs when scientifically necessary. (This provision has been included in § 2.30(s)(4) of the revised rule.) Proposed § 2.35(c) would have allowed the Committee to grant exceptions only when necessary for the accomplishment of the research design, specified in the "research protocol" [ACUP], and explained in detail. The principal investigator would be required to file a report with the Committee explaining the exception in detail. A copy of the report would be required to be kept on file by the facility and to be available for inspection by USDA inspectors or officials of granting agencies.

Under the revised rule, only the Committee is authorized to approve exceptions to compliance with the regulations and standards, however it is made clear that the research facility is ultimately responsible for any exceptions granted.

We received 33 comments objecting to the proposed requirement that the principal investigator first file a written report, and suggesting that an oral report to the Committee is sufficient. We cannot make any changes based upon this comment since the Act specifically requires that exceptions to the standards be detailed and explained in a report and filed with the Committee (7 U.S.C. 2143(a)(3)(E)). The Act also requires a written explanation from research facilities for any deviation from the standards. Because of these specific requirements in the Act, we do not have the authority to require only an oral report instead of a written report.

Six commenters stated that the procedure provided in proposed § 2.30(g) for approval of exceptions to the requirements of proposed § 2.30 (e) and (f) should also be available for exceptions from other requirements in the regulations. We believe that the revised rule is broad enough to cover exceptions from any of the Animal Welfare regulations and will allay the commenters concerns that exceptions to regulations other than § 2.30 (e) and (f) be possible.

Section 2.30(h) Exercise for dogs and psychological well-being of primates. As stated in the discussion of the reassignment of responsibilities from the Committee to the research facility under the heading, "Reorganization of §§ 2.30 and 2.35," the research facility is responsible in this revised rule for establishing written procedures and systems for the exercise of dogs and for the psychological well-being of primates in accordance with the regulations and standards, and for establishing a record system indicating that such a procedure or system is being carried out. This must be done in consultation with the attending veterinarian. (These procedures may be included in the facility's standard operating procedure, although this is not mandatory.) The proposed standards for exercise of dogs and to promote the psychological well-being of nonhuman primates are provided in a related document published elsewhere in this issue. (*See* companion docket no. 87–004.)

We received 357 comments (332 from the research community and 25 from members of the general public) stating that the requirement for establishing these procedures and systems should be implemented by the attending veterinarian, rather than the Committee as originally proposed, to avoid conflicts between the attending veterinarian and the other Committee members. The reassignment of responsibility for these procedures to the research facility removes the possibility of conflict between the Committee and the attending veterinarian. The Committee will still be responsible for inspecting animal areas to ensure that pain and distress are minimized and it is also required to approve of any ACUPs which deviate from the standards of Part 3. These functions should not conflict with the attending veterinarian's consultative role in developing written procedures and systems. No change is made as a result of these comments.

We received 505 comments (480 from the research community and 25 from members of the general public) objecting to the requirement for a separate record system to document that these procedures are being carried out. The requirements for exercise of dogs and for promoting the psychological well-being of nonhuman primates are two of the primary directives of the 1985 amendments to the Act. We believe that a separate record system provides a vital mechanism to ensure compliance with the regulations and to give our inspectors a means of checking for compliance. This is particularly so with regard to exercise for dogs and promoting the psychological well-being of nonhuman primates. Unlike tangible requirements, such as cage sizes and cleanliness which can be observed at all times, there must be written verification that the procedures concerning exercise for dogs and psychological well-being of nonhuman primates are being followed in order to ensure compliance. We believe that the required recordkeeping is reasonable and will ensure compliance. No change is made in the regulations based upon this comment.

Section 2.30(i) Training. The requirement to provide for the training and continuing education of personnel was imposed upon the research facilities in the proposed rule. However, the task of reviewing the status of the training and the qualifications of researchers, and of designating those personnel needing additional training was imposed on the Committee in proposed § 2.35(f). This requirement is also imposed on research facilities in § 2.30(i) of the revised rule, because the Act makes the facilities responsible for training (7 U.S.C. 2143(d)). We have determined, however, that this responsibility should be carried out through the attending veterinarian, since the training will be in areas in which the attending veterinarian has expertise, such as proper drug usage and pre- and post-procedural care. (The proposed rule would require training in proper pre-surgical and post-surgical care of animals. For the reasons set forth in our discussion of § 2.30(e)(6) under the subheading, "Painful procedures," this requirement applies to all procedures in order to ensure adequate veterinary care, and is not limited to surgical procedures.)

Nineteen commenters stated that the proposed training requirements are beyond the scope of the Act. We have considered this comment, but are making no changes based upon it. The training requirements are either specifically stated in the Act or are necessary adjuncts of the areas of animal care in which instruction is required by the Act (7 U.S.C. 2143(d)). For example, the requirement in § 2.30(i)(4)(ix) to provide training in the proper use of pain relieving drugs is a necessary adjunct of "includ[ing] instruction on research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress; * * *" (7 U.S.C. 2143(d)(2)).

We are making some changes in the requirements for annual review of the status and qualifications of personnel who use animals, because other institutional mechanisms exist for discovering deficiencies in the level of training and qualification. We have also eliminated the requirement for training in the area of animal ethics. These modifications are discussed below in this section.

Two commenters noted their support for the proposed training requirements and suggested more stringent training requirements. We believe the training requirements contained in § 2.30(i) are within the scope of the Act and satisfy

the intent of the Act. If, after the regulations are in effect, it appears that more stringent regulations are necessary, we will consider proposing additional or revised regulations.

Seventy-nine commenters suggested that training should be made available to individuals based upon the species of animal they use or some other specific need. Proposed § 2.35(f)(2) would have required that the training "be made available annually or as appropriate to the individuals and their responsibilities" and a similar provision is maintained in this revised rule. We are concerned that the proposed language could be misconstrued as requiring that only the frequency and not the substance of training be appropriate to the individuals and their responsibilities. Section 2.30(i)(2) is clarified in the revised rule to reflect that both the substance of the training must be appropriate to the individuals and their responsibilities, as well as the frequency of the training that is made available to them. Under the rule, the research facilities can determine whether training should be based upon the species of animal used, or whether other criteria should be used, in accordance with their determination of what is appropriate, so long as the areas listed in § 2.30(i)(4) are covered.

We received 560 comments (535 from the research community and 25 from members of the general public) objecting to the requirement of proposed § 2.35(f)(3) that the Committee annually review the status of training and qualifications of researchers who use animals. The commenters stated that this would be costly and impractical. Although responsibility for this review is placed on the research facility in this revised rule, we anticipate that the same objection will be raised, as the facility must bear the cost of the review. Representatives of HHS have pointed out that internal mechanisms exist in research facilities, such as performance appraisals, which would highlight the need for additional training, and that facilities should be afforded an opportunity to satisfy the requirements of the Act by developing monitoring procedures which utilize these existing mechanisms. We agree that some facilities may have adequate means of reviewing the status of training and the qualifications of personnel, and we are revising the requirement for annual review at research facilities. Research facilities could avoid a separate annual review as required by § 2.30(i)(3) in the revised rule, if they have a written policy requiring that they annually review their personnel in the areas of training and qualifications.

We received 434 comments (409 from the research community and 25 from members of the general public) suggesting that the areas of instruction required in paragraph (4) be listed in two groups: one for all employees and one for employees involved with animal care, use, and treatment. By its terms, the training required by § 2.30(i) in the revised rule is limited to those persons involved with animal use, care, and treatment. Those persons who do not have this contact with animals would not be required to undergo the requisite training. Accordingly there is no need to divide the areas identified in § 2.30(i)(4) into two parts as the commenters suggested. Training of personnel who are not involved with animal care, use, and treatment is left to the determination of the research facilities, because it is beyond the scope of the Act.

Proposed § 2.35(f)(4)(i) would require instruction in "[h]umane methods of animal maintenance and experimentation and animal ethics; * * *." Eight commenters suggested that the requirement for instruction in animal ethics be deleted and another 37 commenters suggested substituting "research ethics" for "animal ethics." We agree that the term "animal ethics" invites differing philosophical views over what the substance and content of the instruction should be, making regulation difficult. Therefore, we are deleting the reference to "animal ethics." The remaining required areas of instruction fulfill the intent of the Act.

We received 299 comments (274 from the research community and 25 from members of the general public) objecting to paragraph (4)(xi) of proposed § 2.35(f). As proposed, it would have required instruction in "[o]ther training, techniques, or procedures the Committee, or the Secretary, may feel is necessary." Responsibility for this determination is reassigned to the research facility as part of the reorganization of §§ 2.30 and 2.35. The commenters stated that paragraph (xi) is meaningless for compliance purposes and should be deleted. We disagree. The Secretary must have the flexibility to require training in additional areas if it is determined to be necessary. Also, as scientific knowledge evolves, it could become apparent that additional or different training in new technologies is needed, and the Secretary must have the authority under the regulations to require this training in order to fulfill the intent of the Act.

Except for those changes discussed above, the substance of proposed § 2.35(f) remains as originally proposed. However, responsibility for compliance with the requirement to provide training is placed on the research facility in § 2.30(i) of the revised rule.

Section 2.30(j) Reporting. Proposed § 2.35(b)(2)(iii) would require the Committee to establish a reporting procedure for personnel or employees to report violations of the Animal Welfare regulations, including problems, deviations, or deficiencies with animal housing, care, or use. The Committee would review and investigate reports of violations and would then prepare and file a report at a central location. It would also protect Committee members and personnel from discrimination or reprisal for reporting violations. The Act requires that the Committee file an inspection certification report, including reports of any violations or deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any corrections made (7 U.S.C. 2143(b)(4)(A)). The Act does not specifically mandate that the Committee devise a reporting procedure for personnel to report violations. Accordingly, this responsibility is reassigned to the research facilities in § 2.30(j) of the revised rule. The Committee, however, is still required to review and investigate reports, under the revised rule. The Committee is in the best position to do so because it is established to assess animal care and use, and has inspection authority under the Act. Research facilities are also required to establish the central location for filing reports under the revised rule. This requirement is set forth in § 2.30(m).

We received 367 comments (342 from the research community and 25 from members of the general public) stating that the proposal to require a reporting procedure to report violations or deficiencies to the Committee exceeds the authority of the Act, as the Act refers to training for these procedures only. Section 13(d) of the Act requires each research facility to provide training including instruction on "methods whereby deficiencies in animal care and treatment should be reported." (7 U.S.C. 2143(d).) This directive presumes the establishment of a reporting procedure. The legislative history of the 1985 amendments to the Act which require this training makes this point eminently clear. In the *Congressional Record* of

December 18, 1985, at page S17943, Senator Dole stated:

> [i]t is intended that all personnel be acquainted with the provisions of this Act and instructed to report deficiencies promptly to ensure that the facility is in compliance at all times. No one should be discriminated against for reporting violations of the Act. Veterinary inspectors from the U.S. Department of Agriculture cannot be present on a daily basis. However, their enforcement capability can and should be enhanced by the Institutional Animal Committee and personnel in laboratories must be protected against any reprisal for reporting mistreatment of animals.

The Conference Report included in the *Congressional Record* of December 17, 1985 at page H12421 states, "[a]ll personnel are intended to be acquainted with the provisions of this Act and instructed to report deficiencies promptly to ensure that the institution is in compliance at all times. No employee shall be discriminated against for reporting violations." We believe the Act intended that a mechanism for reporting violations and deficiencies be implemented at research facilities as a vital means of ensuring compliance with the Act and the regulations. The Secretary is authorized to promulgate regulations deemed necessary to effectuate the purposes of the Act, including the reporting of violations and deficiencies. The requirement for a reporting procedure therefore does not exceed the statutory authority.

Two members of the general public and 1 commenter from the research community stated that the reporting provisions should include protection for the employer as well as for employees and Committee members. The legislative history cited above addresses protection against reprisal or discrimination for employees who report violations. It is silent on employers and facilities that report personnel as being in violation of the Act or regulations. The Act intends that facility personnel function as checks on each other and on the facility as a whole, and relies on the facility to monitor its own house. The facilities have the resources to safeguard themselves and their supervisory officials and we do not believe that regulations providing this protection are warranted.

Section 2.30(k) Federal research facilities. Proposed § 2.35(e) would have required federal research facilities to establish an Institutional Animal Care and Use Committee (Committee) having the same duties and functions as nonfederal research facilities except that the Committee would report deficiencies to the head of the federal agency conducting the research instead of to APHIS, and the head of the federal agency would be responsible for all corrective action and for granting of all exceptions to inspection protocol. As stated in the initial paragraphs of the supplementary information to Subpart C, we have determined that it is more appropriate to include this provision in § 2.30 since it is directed to the research entity and not the Committee. It is § 2.30(k) in the revised rule.

We received two comments concerning proposed § 2.35(e) "Federal research facilities," both from members of the research community. The comments stated that "institutional official responsible for animal care and use" should be substituted for "head" of the federal agency, because authority to administer animal care may be delegated to another official in the agency. We disagree and have used the language appearing in the Act. The Department is not involved in a determination by an agency "head" to delegate authority in accordance with agency internal procedure. We cannot by regulation place this authority at a lower level than that legislated by Congress. No change is made in the revised rule.

Section 2.30(1) Reviews. Proposed § 2.35(b)(3)(i) would require the Committee to make all research protocols [ACUPs] and assurance statements required by PHS or other funding Federal agencies available for review upon the request of the Administrator, to assure compliance with the Act. Department inspectors would be required to maintain the confidentiality of the requested material. Under the reorganization described above, the responsibility for responding to a Departmental request ultimately rests with the research facility or responsible institutional official acting on behalf of the research facility, and is included in § 2.30 in the revised rule as subsection (1).

We received 529 comments (504 from the research community and 25 from members of the general public) objecting to the requirement to make all protocols [ACUPs] and assurance statements available to APHIS. Some of the concerns focused on public release of the materials. Others were that the requirement exceeds statutory authority. As to the latter concern, the Secretary has authority under the Act to require production of all ACUPs and assurance statements as part of the authority to require each research facility to show, upon inspection, that the provisions of the Act are being followed (7 U.S.C. 2143(a)(7)). Section 16 of the Act authorizes the Secretary to make investigations or inspections as he or she deems necessary to determine whether any provision of the Act or the regulations and standards have been or are being violated (7 U.S.C. 2146(a)). Review of ACUPs and assurance statements would provide important information and would be key indicators as to whether any of the provisions of the Act or regulations are being violated or have been violated.

We understand the research facilities' concern with public release of these documents, particularly before a violation of the Act or the regulations has been established. We agree in part with commenters who stated that this material should not be retained by USDA and possibly subject to release to the public in response to Freedom of Information Act requests to USDA. Section 2.30(1) is revised to reflect that these materials will not be removed from the research facilities' premises unless there has been an alleged violation or the material is needed for an investigation or other enforcement purposes.

Thirty-eight commenters requested clarification as to when the Administrator could request that "protocols" and assurance statements be made available for review by the Department. These documents would be requested whenever there is reason to believe there may be noncompliance with the Act or the regulations, when needed to investigate possible or alleged violations, and when needed for other enforcement purposes.

Section 2.30(m) Reports. Proposed § 2.35(b)(2)(iv) would require that any reports required by proposed § 2.35 be kept on file at the research facility for at least 3 years and be made available for inspection and review by APHIS inspectors and any funding Federal agency. We did not receive any comments addressing this proposed requirement. We have revised the requirement in this rule, however, to provide that, upon notification from the Administrator, research facilities must retain records for more than 3 years pending completion of an investigation or proceeding, as required by § 2.81. This is a nonsubstantive change because research facilities are subject to the provisions of § 2.81.

Proposed § 2.35(b)(2)(i) would require that the Committee file its inspection certification report at a central location at the research facility. We are including the requirement that research facilities maintain a central location for filing reports.

The proposed rule referred to inspection and review of reports by APHIS inspectors. We have revised

these provisions to provide for inspection and review of reports by APHIS officials as a result of the change in terms used for APHIS personnel, as described in a related document published elsewhere in this issue of the Federal Register, docket no. 88-013, Part 1—"Definition of Terms." The term "APHIS official" as defined in Part 1 would include an APHIS inspector.

The research facility is ultimately responsible for retaining the Committee's reports and assurance statements. Accordingly, this provision has been placed in § 2.30 in the revised rule as paragraph (m). We have also revised it to refer to any reports required by Part 2, instead of § 2.35 as originally proposed, due to the reorganization of §§ 2.30 and 2.35.

Section 2.31 Annual report of research facilities. Proposed § 2.28 requires each research facility to submit an annual report to the Area Veterinarian in Charge. This was proposed under Subpart B—"Registration." We believe it is more appropriate to include this requirement under Subpart C—"Institutional Animal Care and Use Committees and Other Requirements for Research Facilities," since it applies only to research facilities. Accordingly, it is redesignated as § 2.31 in the revised rule. The comments we received concerning the annual report refer to proposed § 2.28 and we will refer to the proposed section and paragraph designations in addressing the substance of those comments.

General. We received numerous comments addressing the annual report required of research facilities, the information we are requiring to be included in the report, and the proposed certifications of the report.

We received 443 comments (417 from the research community and 26 from members of the general public) stating that the proposed regulation exceeds the Department's statutory authority. We believe that the annual report and its contents are not only authorized, but are mandated by the Act. Section 13(a)(7)(A) of the Act states the Secretary "shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this Act are being followed * * *" (7 U.S.C. 2143(a)(7)(A)). The Act goes on to specify information that the research facilities must provide in their report. We believe that the information we are requiring in the report is either specifically required by the Act or is necessary to enable the Department to determine if the facility is in compliance with the Act and the regulations.

We also received 168 comments from the research community objecting that the information required to be provided on the annual report would involve extensive record-keeping and reporting beyond the requirements of the Act. The assurances and information required of research facilities by § 2.28 are required by section 13 of the Act. This information enables the Department to inspect for compliance with the regulations and standards under the Act, and enables the Secretary to submit the comprehensive and detailed annual written report to Congress required by section 25 of the Act (7 U.S.C. 2155).

We received 456 comments (431 from the research community and 25 from members of the general public) requesting that the annual report be revised and simplified. They also stated that § 2.28 as proposed would require redundant assurances. We agree that simplification of the report is desirable, and we have modified the report requirements in the revised rule.

One commenter from the research community stated that the annual report should be revised to include all pertinent information. We are currently reviewing the annual report form, Form VS 18-23. The form will be updated and revised as necessary to include all information that will now be required by the regulations.

Two commenters from the research community suggested that we incorporate the registration update required by § 2.25 in the annual report. These two reporting requirements serve very different purposes. We believe that combining them would create problems rather than simplify matters. The registration update is required of all registrants every 3 years so that the Department can maintain accurate records of the identity and location of registrants. The annual report is, as its name indicates, a yearly report required only from research facilities. Not all registrants are research facilities. If the two different reporting requirements were combined for the research facilities, yet another reporting system would have to be devised for those registrants who are not research facilities, to avoid unnecessary or inapplicable information collection. We believe it prudent to keep these two reporting requirements distinct.

Proposed § 2.28(a). As proposed, § 2.28(a) would require the Chief Executive Officer (CEO) of the facility, the attending veterinarian, and the chairman of the Institutional Animal Care and Use Committee (Committee) to sign the annual report. Proposed § 2.28(b)(9) would require a statement by the CEO that the attending veterinarian and the Committee have the authority to enter any animal area to carry out their responsibilities, that the Committee has satisfactorily carried out its responsibilities, and that the facility is in compliance with the Act, regulations, and standards. Section 2.28(c) would require the attending veterinarian and the Committee chairman to certify the annual report, in accordance with §§ 2.40(e)(2)(iii) and 2.35(g) of the proposed rule.

Fifty-five commenters from the research community stated that only the CEO should be required to sign the report. Ninety-six commenters from the research community stated that reference to the "CEO" in proposed § 2.28(b)(9) should be changed to "institutional official" to coincide with the PHS Policy. Four commenters from the research community stated that the report and assurances are the responsibility of the facility and should not require other certification. We agree that the assurances of compliance required in the report are the responsibility of the institution, not the Committee Chairman or the attending veterinarian, because it is the ultimate responsibility of the facility to ensure compliance with the Act and the regulations. Therefore, we are revising the rule to require that the annual report be signed only by the CEO or a "responsible institutional official with authority to bind the facility." This revision means that it needn't be the CEO who signs the report, however the institutional official who does sign the report must be authorized to bind the facility. We originally proposed in § 2.28(a) to require the signature of all three individuals as a means of detecting noncompliance at facilities. For example, if an attending veterinarian refused to sign the report, we would suspect that he or she was, in some way, not satisfied with the facility's administration of the program of veterinary care. In order to satisfy this concern, which we still have, we are also amending proposed § 2.28(a) to include a mechanism for including all dissenting views in the annual report. This is described in greater detail below under the discussion of proposed § 2.28(c).

Proposed § 2.28(b). As proposed, § 2.28(b)(1) states that the annual report shall "[s]how that professionally acceptable standards governing the care, treatment, and use of animals, * * * were followed by the research facility; * * *". We received 411 comments (386 from the research community and 25 from members of the

general public) objecting to use of the word "show" and stating that the report can only state this fact, not show it. We received 168 comments from the research community suggesting that we change "show" to "ensure" or "assure." A number of the commenters pointed out that facilities must show their compliance with the Act and regulations through inspections, as required by section 13 of the Act (7 U.S.C. 2143(a)(7)). We agree with the commenters and have changed "show" to "assure" in § 2.31(b)(1) of the revised rule. We have also revised the rule to require assurance that professionally acceptable standards were followed during pre- and post-procedural care, in place of pre- and post-surgical care, because adequate veterinary care must be provided for all procedures in accordance with the Act.

Proposed § 2.28(b)(2) requires an assurance in the annual report that the principal investigator has considered alternatives to painful procedures. We received 313 comments (288 from the research community and 25 from members of the general public) suggesting that we combine this assurance with proposed paragraph (b)(7) and that we clarify paragraph (b)(2). Proposed paragraph (b)(7) requires the names and numbers of animals upon which painful procedures were conducted and pain relieving drugs were withheld. A detailed statement of explanation as to why drugs were not used must be attached to the annual report. We disagree with the commenters. Section 13 of the Act requires that alternatives be considered for all procedures likely to produce pain or distress (7 U.S.C. 2143(a)(7)(B)(i)). This requirement applies to all painful procedures, whether or not the pain is relieved. Accordingly, paragraph (b)(2) requires assurances that alternatives were considered with respect to all painful procedures, regardless of whether or not pain relieving drugs are used or withheld. Proposed paragraph (b)(2) is far broader than the limited circumstances covered in paragraph (b)(7), which is limited to painful procedures for which pain relieving drugs (anesthetics, analgesics, or tranquilizing drugs) are withheld.

By design, the assurance required in proposed paragraph (b)(2), that alternatives to painful procedures were considered, precedes proposed paragraphs (b) (5) and (6) which concern painful or potentially painful procedures. Proposed paragraph (b)(5) pertains to procedures involving no pain, distress, or use of pain relieving drugs. Proposed paragraph (b)(6) pertains to painful procedures for which pain relieving drugs were administered. The assurance required in § 2.28(b)(2) would apply to the procedures in the succeeding paragraphs. If the requirement for assurance that alternatives to painful procedures have been considered were combined with proposed paragraph (b)(7) it could be construed as pertaining only to those procedures for which pain relieving drugs are withheld, contrary to the requirement of the Act. For this reason, no changes will be made to paragraph proposed (b)(2) in the revised rule, or to its placement within the section.

Although we did not receive any comments concerning the specific provisions of proposed § 2.28(b)(3) which requires assurance that the facility is adhering to the standards and regulations under the Act and that an explanation for any deviation from them be attached to the annual report, we are revising it to include assurance that the facility required that exceptions to the standards and regulations be specified and explained in an ACUP and approved by the Committee. We believe that these changes are consistent with the requirements of section 13(a)(7) of the Act (7 U.S.C. 2143(a)(7)) and with §§ 2.30 and 2.35 of this revised rule.

We received 391 comments (366 from the research community and 25 from members of the general public) objecting to the requirement of proposed paragraph (b)(4) that the annual report state the location of facilities where animals are housed or used in actual research, testing, teaching, or experimentation. One commenter stated a concern that if facilities must provide the specific sites within the facilities where animals are held, the information would be accessible to the public through the Freedom of Information Act and could compromise their security.

It is necessary for APHIS to know the location of animals at research facilities in order to inspect all animal sites, as required by the Act. This information is essential for enforcement purposes, as evidenced by the case of a research facility at a major university which maintained nonhuman primates for years, hidden from APHIS inspectors, by failing to disclose the animal site to APHIS.

We believe the commenters' concerns about revealing the location of animal areas are unwarranted. This information has been required in the annual report since the regulations were revised in 1972 to incorporate the 1970 amendments to the Act, and there is no indication that a facility's security was compromised because third persons learned the whereabouts of laboratory animals through Freedom of Information Act requests. Furthermore, once APHIS has inspected a facility, an inspection form is completed which details the location of animals at each site. This form is filed with the Agency and may potentially be disclosed through Freedom of Information Act requests. Therefore, leaving this information out of the annual report may not prevent third persons from obtaining the information.

We are clarifying proposed paragraph (b)(4) in the revised rule to also require the location of the facility or facilities where animals are held for future use in research, testing, teaching, or experimentation, to avoid any confusion that we are only requiring this information for animals in actual use.

Since deletion of this requirement would not have the effect intended by the commenters, and since the information is necessary for the Department to comply with the Act, paragraph (b)(4) will remain as proposed except for the above clarification.

Thirty-five commenters from the research community stated that facilities should be required to identify animals by their scientific names on the annual report, rather than by their common names, in order to obtain factual information and for accuracy in the collection and utilization of the information. One commenter stated that this information is necessary for the public and the legislators, so that policy regarding the use of animals in research can be appropriately established. Proposed paragraphs (b) (5) through (8) of § 2.28(b) would require facilities to "[s]tate the common names and the numbers of animals" maintained or used for the various purposes described in those paragraphs. The requirement to identify animals by their common names has been part of the annual report since the report was first established under the 1970 amendments to the Act. Common names are likewise used in the Department's annual report to Congress. No problems or difficulties arising from the reporting system for facilities or the use of common names of animals have become apparent to us. Based upon our experience, we do not believe that it is necessary to require use of scientific names on annual reports. We received 92 comments from the research community stating that the requirement of proposed § 2.28(b)(6) to report the number of animals "upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the

animals" with the use of pain relieving drugs, and of proposed § 2.28(b)(7) to report the number of animals similarly used but for which the use of pain relieving drugs would adversely affect the procedures and are withheld, exceeds the Department's statutory authority. Proposed paragraph (b)(7) also provides that "[a] detailed statement on the procedures producing pain or distress in these animals and explaining the reasons such drugs were not used shall be attached to the annual report." Thirty commenters from the research community objected to this requirement as exceeding the statutory authority, and 369 commenters (344 from the research community and 25 members of the general public) objected to this requirement and suggested that we change it to conform with the statutory language which requires "information on procedures likely to produce pain or distress in any animal * * *" (7 U.S.C. 2143(a)(7)(B)).

We disagree with these commenters; we have the statutory authority to require the information in the form proposed.

One of the stated purposes of the Act is to "insure that animals intended for use in research facilities * * * are provided humane care and treatment; * * *" (7 U.S.C. 2131). Another is to provide requirements to "ensure that animal pain and distress are minimized * * * with the appropriate use of anesthetic, analgesic, tranquilizing drugs, or euthanasia; * * *" (7 U.S.C. 2143(a)(3)(A)). Accordingly, section 13(a)(3)(E) of the Act allows "exception to such standards * * * only when specified by research protocol and that any such exception shall be detailed and explained in a report outlined under paragraph (7) and filed with the Institutional Animal Committee" (7 U.S.C. 2143(a)(3)(E)). Paragraph (7)(A) of section 13(a) of the Act mandates that the Secretary "shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this Act are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation." (7 U.S.C. 2143(a)(7)(A)). Paragraph (7)(B) of section 13(a) requires research facilities to provide:

(i) Information on procedures likely to produce pain or distress in any animal and assurances demonstrating that the principal investigator considered alternatives to those procedures;

(ii) assurances satisfactory to the Secretary that such facility is adhering to the standards described in this section; and

(iii) an explanation for any deviation from the standards promulgated under this section. (7 U.S.C. 2143(a)(7)(B)).

We believe that these provisions of the Act authorize the Secretary to require the common names and the numbers of all animals upon which painful procedures were conducted. The required information is necessary to enable us to determine, upon inspection and through annual reports of facilities, that the Act is being complied with, and that the intent of Congress—to ensure that research animal pain and distress are minimized—is being advanced. The Agency must be able to make this determination in order to fulfill our annual reporting obligation to Congress, in accordance with section 25 of the Act (7 U.S.C. 2155).

The additional requirement in proposed § 2.28(b)(7) for a detailed statement explaining the reasons why pain relieving drugs, which are required by the Act unless it is scientifically necessary to withhold them, were not used, is mandated by section 13 of the Act, as set forth above. The statement is a necessary component of a facility's assurance that the provisions of the Act are being followed, "that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation," and that the "facility is adhering to the standards * * *" (7 U.S.C. 2143(a)(7) (A) and (B)). Current § 2.28(a)(4) contains a similar requirement for a "brief statement" explaining why pain relieving drugs have been withheld. We believe the proposal to require a detailed statement of reasons for not using pain relieving drugs reflects the intent of Congress in amending the Act and that this requirement is mandated by section 13 of the Act (7 U.S.C. 2143(a)). For these reasons, paragraphs (b) (6) and (7) remain as proposed in § 2.31 of the revised rule.

Six commenters from the research community stated that the requirement of proposed § 2.28(b)(8) to report the number of animals being bred, conditioned or held for use, teaching, testing, experiments, research, or surgery, but not yet used, should be revised to reflect more accurately the number of animals held for use but not used. One commenter expressed concern that the number of unused animals at a facility is highly variable and changes daily so that the annual report would not provide an accurate figure. It would also not be an accurate means of determining the number of animals held by all facilities since animals are transferred between facilities and would be counted multiple times. In addition, some animals may be used in a procedure, and then held for another use, and would be counted at least twice: once as an animal used for teaching, testing, experiments, research, or surgery under paragraphs (b) (5), (6), or (7), and a second time as an animal being bred, conditioned, or held for use, teaching, testing, an experiment, research, or surgery under paragraph (b)(8).

We do not believe that it is necessary to revise paragraph (b)(8). That paragraph requires an accounting of all animals that have not yet been used and are being bred, conditioned, or held for future use by a facility. It is true that a transferred animal would be included in the annual report of each facility in which it is placed since it would be "new" to that facility. It is also true that an animal that was used in a procedure that is completed and is being held for use in another procedure would be included under paragraph (b)(8).

We received 314 comments (289 from the research community and 25 from members of the general public) suggesting that the substance of paragraph (b)(8) should be combined with paragraph (b)(4) so that there is a single requirement for reporting the number of animals at a facility. We disagree. Proposed paragraph (b)(4) of § 2.28 pertains to location of animals at a facility, not the number of animals. These are two distinct reporting requirements which the Department uses separately in the Department's annual report to Congress. Combining these requirements would complicate our reports and would not reduce the effort required of reporting facilities to present this data. Since there would be no beneficial effect gained from adopting the commenters' suggestion, both requirements remain in the revised rule.

Proposed paragraph (b)(9) of § 2.28 would require a statement by the CEO in the annual report stating: (1) That the attending veterinarian and the Committee members have authority to enter any animal area in the facility at any reasonable time to carry out their responsibilities under the regulations; (2) that the Committee has satisfactorily carried out its responsibilities; and (3) that the facility is in compliance with the Act, regulations, and standards. We received 305 comments (280 from the research community and 25 from members of the general public) stating that the statement concerning access by

the attending veterinarian and the Committee members to animal areas is redundant and unnecessary because it would be included within the assurances of compliance required in proposed paragraphs (b) (1) and (3). The commenters also objected to requiring the CEO's signature. We believe it is appropriate to require a separate statement by the CEO addressing these three concerns. Although paragraphs (b) (1) and (3) of proposed § 2.28 generally address compliance with the standards and regulations, we feel it is important that the CEO or responsible institutional official with authority to bind the facility bear responsibility for assuring that the statements made in the annual report are accurate and that the facility is in compliance. We believe that this accountability is necessary to ensure that the annual reports are meaningful and reliable.

For the reasons provided above in connection with proposed § 2.28(a), either the Chief Executive Officer or the "responsible institutional official with authority to bind the facility" may make the required statement in the annual report, and § 2.31(b)(9) is revised accordingly, in response to the comments received.

Thirty-seven commenters from the research community stated that the term "reasonable time" in proposed § 2.28(b)(9) should be defined, and 344 commenters (319 from the research community and 25 members of the general public) stated that the Committee members should not be allowed unrestricted entry to animal areas at any time if entry would interfere with ongoing research or the protection of proprietary information. Thirty commenters suggested that the Committee members and the attending veterinarian should have "reasonable access" to animal areas instead of "authority to enter any animal area, at any reasonable time" as proposed. The commenters stated that allowing reasonable access would prevent undue disturbance of the animals or controlled environmental conditions, prevent interference with research, and would protect proprietary information. The commenters suggested that "reasonable access" would require consultation with the principal investigator before entry into an animal area if research is being conducted, unless the Committee has reason to believe there is a problem related to animal welfare.

We do not believe that "reasonable time" requires additional clarification in the regulations. Research facilities can clarify what is a reasonable time through their written procedures or through guidelines issued by the CEO or responsible institutional official with authority to bind the facility. As previously explained in the discussion of Subpart C under the subheading, "§ 2.30(c)," it is not our intent to interfere with ongoing research, but we feel strongly that the Committee must have authority to enter all animal and research areas at any reasonable time without having to fulfill formal procedures as a prerequisite, and that the attending veterinarian must have authority to enter all animal or research areas at any time in order to ensure compliance with the program of adequate veterinary care. Section 2.31(b)(9) is revised to reflect this change. We do not intend that the Committee and attending veterinarian make a practice of barging into animal areas, and in this respect we agree that the principal investigator should be consulted as the commenter suggests. We do not believe it is appropriate to include a requirement for this in the regulations, however. Each facility is free to establish guidelines or a policy regarding consultation and to establish its own written procedures. We will retain the requirement that the annual report contain a statement, signed by the CEO or responsible institutional official, certifying that the Committee members have authority to enter any animal or research area at any reasonable time in order to carry out their responsibilities, and that the attending veterinarian is permitted access to all animal or research areas at any time.

Proposed § 2.28(c). We proposed in § 2.28(c) that the annual report be certified by the attending veterinarian and the Committee Chairman, in addition to being signed by the CEO under paragraph (a). We also proposed in § 2.28(c) that the annual report indicate the concurrence or nonconcurrence of the nonaffiliated member of the Committee.

Four commenters from the research community stated that the report and its assurances should be the responsibility of the CEO and should not require any other certifications. We received 370 comments (345 from the research community and 25 from members of the general public) stating that the entire paragraph should be deleted since the signature of the CEO required in paragraph (a) would be sufficient. One commenter was concerned that the proposed certification requirements improperly placed the burden of responsibility for the facility's compliance on the attending veterinarian and the Committee Chairman, and that at most they should be required certify to performance of their duties and fulfillment of their responsibilities. Others were concerned with the veto power given the attending veterinarian and the Committee Chairman, and the potential for abuse. One commenter noted that requiring the attending veterinarian to certify the annual report could place members of the Committee at odds with each other by giving one member the power that the Committee as a whole should have, and that this would undermine the ability of the Committee to perform its intended role.

Having considered the comments, we have determined that only the CEO or responsible institutional official with authority to bind the facility need sign and certify the annual report. Therefore, we are deleting the requirement from proposed § 2.28(c) that the attending veterinarian and Committee Chairman certify the annual report. The requirement that the CEO or responsible institutional official sign the annual report is already contained in paragraph (a) of § 2.31 in the revised rule, and we are adding a requirement that this official must also certify the report.

We received 179 comments from the research community stating that the requirement contained in proposed § 2.28(c) that the nonaffiliated member of the Committee indicate concurrence or nonconcurrence with the annual report should be deleted. Three members of the general public and one member of the research community stated that the annual report should reflect all dissenting opinions, and not single out the nonaffiliated member of the Committee. Some of the commenters pointed out that the Act, in Section 13, provides a mechanism for filing a minority view in connection with the inspection certification report prepared by the Committee (7 U.S.C. 2143(b)(4)(A)). The commenters further point out that the Committee report is separate from the annual report of the facility, and that the nonaffiliated member's view would appear to be irrelevant for purposes of submitting the facility's annual report.

Upon reconsideration of the requirement, we agree with the commenters that the emphasis on the concurrence or nonconcurrence of the nonaffiliated member of the Committee should be broadened to provide for the concurrence or nonconcurrence of any member of the Committee. We have revised this requirement to give all members of the Committee an equal opportunity to express a minority or nonconcurring view. To assure that the

members are afforded this opportunity, the CEO or responsible institutional official with authority to bind the facility will be required to certify that he or she circulated the report to the Committee members for their review and that each was advised that they could add a minority report or indicate their nonconcurrence. We intend that the report would be circulated to each member with an attached routing slip containing a blank space in which the member could indicate that he or she read the report and concurred or did not concur, and that he or she was attaching a minority report to be included with the annual report. The slip would be replaced with a new blank slip for each Committee member's review. In this manner, confidentiality between the responsible institutional official and between each member of the Committee would be maintained. The annual report must contain a space in which the CEO or responsible institutional official states that all Committee members had an opportunity to indicate nonconcurrence, and to state whether any minority reports are attached. As stated above, the CEO or responsible institutional official would be required to certify these statements.

We believe that this requirement will allow each member an opportunity to express dissent from the annual report and that his or her opinion will be forwarded to the Department. This is particularly important for ensuring that the nonaffiliated member is not excluded from Committee functions. The nonaffiliated member's purpose is to provide representation for general community interests, and this may or may not result in that member being at odds with the other members of the Committee. We are aware of circumstances where the nonaffiliated member of the Committee has been prevented from meaningful participation in Committee functions or shut out of Committee meetings altogether because he or she presents a contrary or unpopular view. This mechanism should alert the Department to the need for further inspections or investigations of the facility. Accordingly, § 2.28(c) is revised to provide for the concurrence or nonconcurrence of all members of the Committee with the annual report.

Section 2.35 Institutional Animal Care and Use Committee

The remaining provisions of § 2.35 in the revised rule are those areas either specifically assigned by the Act to the Committee or necessary to implement the provisions of the Act which mandate Committee action. Many of the comments we received concerning § 2.35 as proposed have been addressed under the headings, "Introduction," "General," and "Reorganization of §§ 2.30 and 2.35." The comments we received addressing the remaining provisions are discussed below. Unless otherwise noted, the comments were received from members of the research community.

General. We received a number of comments addressing proposed § 2.35 and the role of the Committee in general. Some comments were made concerning use of the Committee as an instrumentality of the facility, both for enforcing the regulations and for performing tasks assigned to the facilities by the Act. The reassignment of responsibilities is fully detailed in a preceding section of this supplementary information, under the heading, "Reorganization of §§ 2.30 and 2.35."

Two commenters from the general public stated that the Committees were not given adequate authority in the proposed regulations. The Act prescribes the areas of authority delegated to the Committee and the revised rule is in accordance with the Act. The research facilities remain free to delegate authority to the Committee to perform additional duties on behalf of the facility. We believe it is best to leave this determination to the research facilities.

Fourteen members of the general public commented that the Department should promulgate national standards, instead of delegating responsibility to the Committees. We are proposing to do so in the proposed rule for Part 3—"Standards," published elsewhere in this issue. (*See* companion docket no. 87–004.) Part 3 provides the standards for the humane handling, care, treatment, and transportation of different animals covered by the Act. The Act requires that the Committees inspect the facilities for compliance with the Act and regulations and assess and report on animal care at the facility. The Committee is necessarily responsible for approving deviations from the standards as part of its duties under the Act; however it does not set the standards. We believe the concern of the commenters has been addressed in proposed Part 3.

We received 168 comments objecting to proposed § 2.35, on the basis that it would require extensive recordkeeping and reporting requirements beyond those required by the Act. We acknowledge that § 2.35 will add new recordkeeping and reporting requirements, however, these are all mandated by the Act and are necessary in order to assure compliance with the Act, regulations, and standards.

Membership. We received 2 comments from members of the general public suggesting that the regulations provide protection for Committee members from possible reprisals. Similar committees have existed in accordance with the PHS Policy at institutions receiving grants or awards under the Health Research Extension Act of 1985, without incident, to our knowledge. We do not feel it necessary to include regulations to protect Committee members at this time.

Two commenters stated that having the chief executive officer (CEO) of the research facility select the Committee members, as proposed in § 2.35(a)(2), biases the Committee. Section 13(b)(1) of the Act states that "[e]ach Committee shall be appointed by the chief executive officer of each such facility * * *" (7 U.S.C. 2143(b)(1)). This is not a matter within the Department's discretion and the regulation will necessarily remain as proposed.

We received 465 comments (440 from the research community and 25 from members of the general public) stating that the CEO should be allowed to delegate his or her responsibilities under the Act. Delegation of authority is a matter left to the facilities in accordance with their charter and by-laws. Delegation should only be to an administrative official who is not involved in the actual conduct of research, however, in order to comply with the intent of the Act that the Committee members be selected by a legally responsible official who is in a position to select a suitable Committee as described by the Act. No change is required in the regulations since this is an internal institutional matter.

Paragraph (a)(4) of proposed § 2.35 states that Committee members "shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility." One commenter expressed concern that the paragraph seems to state that each individual Committee member must possess "expertise" in animal care, treatment, and practices in experimental research. The commenter recommended that the paragraph be clarified to state that the Committee as a whole must have this expertise, but not each and every single member. We disagree with the commenter. The plain language of paragraph (a)(4) is sufficiently clear and is taken from the Act which provides that Committee members must have sufficient ability to assess animal care, and related matters. Committee members must possess some knowledge of animals, but "expertise" in these

areas is not required. This ability is required for each of the Committee members, not just for the Committee as a whole. Another commenter stated that "special" ability to assess animal care should not be required. It is not. Paragraph (4) requires "sufficient" ability to assess animal care, not "special" ability. Section 2.35(a)(4) remains as originally proposed.

Paragraph (a)(5)(i) of proposed § 2.35 states that of the Committee members, "At least one shall be a Doctor of Veterinary Medicine who is the attending veterinarian for the research facility and who is accredited by the U.S. Department of Agriculture in accordance with regulations issued by the Secretary under the Animal Welfare Act; * * *." As explained in a related document published elsewhere in this issue of the Federal Register, docket no. 88-013, Part 1—"Definition of Terms," we are removing references to "accreditation" from these regulations pending the Department's renaming and development of standards for the Animal Welfare "accreditation" program.

We received 398 comments (373 from the research community and 25 from members of the general public) stating that research facilities should be given the flexibility of assigning another staff veterinarian to the Committee in place of the attending veterinarian. There is nothing in the Act or regulations to prevent research facilities from delegating the duties of the attending veterinarian on the Committee to another veterinarian; however, final responsibility for those duties rests with the attending veterinarian. Section 2.35(a)(5) is revised to clarify that the duties of the attending veterinarian may be delegated to a staff veterinarian.

Proposed paragraph (a)(5)(ii) of proposed § 2.35 would require that of the Committee members, "At least one shall not be affiliated in any way with such facility other than as a member of the Committee and shall not be a member of the immediate family of a person who is affiliated with such facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals." The requirement to have a nonaffiliated Committee member is contained in section 13 of the Act (7 U.S.C. 2143(b)(1)(B)). We received many comments concerning the selection of the nonaffiliated member, particularly from the general public. We received 1,518 comments from members of the general public stating that the regulations should ensure that the nonaffiliated member of the Committee is a vigorous and effective community representative and should not be required to possess the medical ability to assess animal care. In other words, any person interested in the humane use of animals could serve on the Committee as the nonaffiliated member. One commenter from the research community suggested that the nonaffiliated member be selected from a list of candidates nominated by recognized humane groups. Under the statute, and as provided in the regulations, the CEO of the research facility appoints the members of the Committee. Other than the criteria provided by the Act and the regulations promulgated under the Act, we do not feel it is appropriate to dictate the manner of selection or to define further the members' attributes. Neither the Act nor the regulations require that the nonaffiliated member be a veterinarian or medically trained.

Nine members of the general public and 1 commenter from the research community stated that there should be more than one nonaffiliated member serving on the Committee. The Act requires that "at least one member—(i) shall not be affiliated in any way with such facility other than as a member of the Committee * * *" (7 U.S.C. 2143(b)(1)(B)(i)). The research facility can determine to have more than one nonaffiliated member but only one is statutorily required. Section 2.35(a)(5)(ii) remains as originally proposed.

Proposed paragraph (a)(6) of § 2.35 would provide that "[i]f the committee consists of more than three members not more than three members shall be from the same administrative unit of such facility; * * *." We received 465 comments (440 from the research community and 25 from members of the general public) requesting that the term "administrative unit" be defined. We have done so in a related document, docket no. 88-013, Part 1—"Definition of Terms," published elsewhere in this issue. The term "administrative unit" would mean the following:

> The organizational or management unit at the departmental level of a research facility.

Paragraph (7) of proposed § 2.35(a) requires that the facility maintain a current list of Committee members containing their names, degrees, positions, qualifications, addresses, and telephone numbers. The attending veterinarian must maintain a copy of the current list and it must be available for inspection by APHIS officials We received 492 comments (467 from the research community and 25 from members of the general public) stating that home addresses and telephone numbers of the Committee members should not be a part of the records accessible to the public and 108 comments stating that only the Committee Chairman's business address should be required rather than the home addresses of all the Committee members. We agree that the list need not contain the home addresses and telephone numbers of the Committee members and that only the Committee Chairman's business address and phone number should be required. Paragraph (7) is revised to reflect this change.

Duties and responsibilities—1. *General.* Proposed § 2.35(b) specifies the duties and responsibilities that the Committee must perform in accordance with the Act. A number of the duties that were contained in this proposed section were not imposed on the Committee by the Act, and have been reassigned to the research facility. A more complete explanation of the reassignment of duties and responsibilities, and precise section references are contained under the heading, "Reorganization of §§ 2.30 and 2.35."

2. *Inspections.* In the supplementary information to the proposed rule, we invited comments addressing how inspections could be carried out at research facilities having a large number of animal sites and study areas. We received 289 comments stating that the Committee should be allowed to delegate inspection and/or review responsibilities to a subcommittee or to other personnel, and that their inspection reports could then be evaluated by a quorum of the Committee. We also received 485 comments (460 from the research community and 25 from members of the general public) urging APHIS to consult with officials of the U.S. Public Health Service on requirements for Committee inspection before promulgating a final rule. The commenters felt that this would be both helpful for the research facilities, which would have to comply with both the Animal Welfare regulations and the PHS Policy on Committee inspections if they receive grants or awards under the Health Research Extension Act of 1985, and for APHIS since the Policy provides guidelines for the accomplishment of inspections and evaluations. As pointed out by some commenters, at most facilities the same Committee will be responsible for complying with the Animal Welfare regulations and the PHS Policy.

Representatives from HHS advised the Department that the PHS Policy

allows the Committee to determine at its discretion "the specific means to accomplish the semiannual evaluation of institutional programs and facilities, however, the IACUC remains responsible for the accuracy and adequacy of the evaluation and report." Facilities can work within their existing organizational structures to accomplish the requisite inspections and evaluations. Under the PHS Policy, the IACUC can appoint a subcommittee or designate personnel to perform the inspections, as 289 commenters suggested.

Having consulted with HHS and having considered the comments we received, we agree that the Committee should be able to appoint subcommittees composed of at least 2 Committee members to perform inspections. We have revised § 2.35(b) in this rule to allow each Committee at a research facility to designate a subcommittee to perform inspections, however, no Committee member who wishes to participate in an inspection may be excluded from participation in that inspection. The right of each Committee member to participate in any inspection conducted under Subpart C is set forth in § 2.35(b)(1)(v) of the revised rule. Section 13 of the Act requires that all formal actions of the Committee must be performed by a quorum of the Committee, and inspections are specifically included as formal actions (7 U.S.C. 2143(b)(2)). In order to satisfy the Act, § 2.35 is further revised to require the subcommittees to present their findings and recommendations, including inspection certification reports, and Committee recommendations based upon inspections, to a quorum of the Committee for formal action.

One commenter stated that the Committee should have the authority to suspend activities as it does under the PHS Policy. We agree with the commenter that painful procedures that are not in compliance with the Act and regulations should be suspended and that this can be accomplished through the Committee. Under the PHS Policy, the Institutional Animal Care and Use Committee may suspend an activity that it previously approved, if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the NIH Guide for the Care and Use of Laboratory Animals, the institution's Assurance, or the requirements of the PHS Policy which must be met in order for a proposed research project or a significant change in a research project to be approved.

We believe that authority to suspend approval of ACUPs is necessary for the Committee to function effectively and to act on behalf of the research facility in monitoring compliance. For this reason, we proposed to include in the assurance statement required from the Committee as part of its inspection report, a statement that all painful procedures are in accordance with the "research protocols" [ACUPs] approved by the Committee and any approved changes to the "research protocols" [ACUPS], and that if the procedures "are not in accordance with the approved 'protocol' [ACUP] that the investigator(s) has been instructed to cease such methods and procedures immediately and to comply with the 'protocols' [ACUPs], procedures, and practices that were approved by the Committee." (Proposed § 2.35(b)(2)(i)(D)). We have added paragraph (iv) to § 2.35(b)(1) in this revised rule to clarify that the Committee has authority to withdraw its approval. The effect of Committee withdrawal of approval is provided in § 2.35(b)(3) in the revised rule.

The research facility is responsible for directing that the research, testing, or teaching cease, otherwise the facility would not be in compliance with the regulations. We are requiring in § 2.35(b)(1)(iv) that the Committee direct the CEO to instruct the principal investigator to cease immediately any research, testing, or teaching involving pain to animals that is not in compliance with the approved ACUP, because it is the research facility's responsibility to direct cessation of activities that are not in accordance with the approved ACUP. In order to ensure that there is no added delay in ordering cessation of such activities, we are requiring that the Committee notify the CEO or responsible institutional official of noncompliance with an approved ACUP involving a painful procedure in its deficiency notification report, as provided in § 2.35(b)(2)(ii).

Forty-four commenters objected to the proposed requirement of § 2.35(b)(1)(i) that the Committee inspect all animal study areas and animal facilities at least twice a year, no more than 6 months apart, stating that it is too specific. Section 13(b)(3) of the Act requires that the Committee conduct inspections "at least semiannually" (7 U.S.C. 2143(b)(3)). We proposed that the inspections be conducted no more than 6 months apart to ensure that the underlying purpose for requiring semiannual inspections is carried out, that is, to ensure that throughout the course of the year each animal area is in compliance with the Act and the regulations. The utility of the inspections is maximized if neither too much nor too little time elapses between inspections. The PHS Policy requires the Institutional Animal Care and Use Committee to inspect the institution's animal facilities at least once every 6 months. This too seems designed to ensure that the twice yearly inspections are effectively spaced out over the course of the year, and is consistent with the proposed rule.

We are revising the requirement for twice yearly inspections to provide that inspections must be performed "at least twice a year, 6 months apart" rather than "no more than 6 months apart" as proposed. We are not requiring that inspections be performed at precise 6-month intervals to the day, but rather that they be performed at some time during the month or 30-day period in which the Committee performs its inspections. We believe that this requirement, as revised, allows facilities sufficient flexibility and time to conduct inspections. We are also revising the regulations to require that at research facilities maintaining multiple animal sites, Committee inspections of all animal sites and animal facilities must be completed within 30 days of commencing the first site inspection so that the Committee can complete and file a comprehensive inspection report. This requirement is necessary for APHIS officials and inspectors to have complete and current inspection reports to review when inspecting research facilities. This requirement is contained in § 2.35(b)(1)(vi) of the revised rule.

We received 307 comments (282 from the research community and 25 from members of the general public) suggesting that first priority for inspections should be given to areas for which exception requests have been submitted in accordance with proposed § 2.35(b)(1)(iii). We appreciate the concern that those animal study areas may require additional attention to ensure that they are in compliance with the Act and the regulations; however, the Act requires at least semiannual inspection of all animal study areas. There is no provision in the Act for assigning priorities to the order of inspections of the different animal study areas—they must all be inspected. The research facility may decide the order of inspections.

3. *Reports.* Under proposed § 2.35(b)(2), the Committee is directed to file an inspection certification report after each inspection which contains the following: (1) The date the inspection was made; (2) the signature of a majority of the Committee members and any minority views of the Committee; (3)

reports of violations of the regulations, standards, or assurances; (4) deficiencies in animal care or treatment; (5) Committee findings and recommendations; (6) any deviations from originally approved "protocols" [ACUPs] that adversely affect animal welfare; (7) notification to the facility of conditions, deviations, or deficiencies; (8) corrections made by the facility; and (9) any other information pertinent to the activities of the Committee and to the animal facilities. The report must also include an assurance statement by the Committee that its members have reviewed all painful procedures using animals and that the procedures are in accordance with approved ACUPs or approved changes to the ACUPs, and, if the procedures are not in accordance with approved ACUPs, that the investigator has been instructed to cease those practices immediately and to comply with the approved ACUPs.

We have revised the proposed rule to require that all inspection certification reports must be completed and filed by the Committee in a timely fashion. We believe that 10 business days from completion of the site inspections required under § 2.35(b)(1) is a reasonable timeframe to impose on the Committee and that it is necessary to ensure that the required information is on file and is current.

We have also revised the rule to reflect the fact that subcommittees of at least 2 Committee members may perform inspections. This is provided in § 2.35(b)(1)(i) of the revised rule. The subcommittee must present its findings to a quorum of Committee members for formal action, as required under § 2.35(b)(2)(i) of the revised rule.

Under proposed § 2.35(b)(2)(ii), the Committee must notify the research facility of deficiencies found during an inspection. If the deficiencies remain uncorrected 30 days after notification and opportunity for correction, the Committee must notify the Administrator and any funding Federal agency and provide them with a copy of the report and the notification given to the facility. The Committee must also provide any APHIS inspector and any funding Federal agency of the project with a copy of any report showing deficiencies in complying with the regulations and standards which remain uncorrected.

We received 471 comments (446 from the research community and 25 from members of the general public) objecting to the requirement of proposed § 2.35(b)(2)(i) that the Committee's inspection certification reports be available to APHIS officials and to officials of funding Federal agencies for copying. Under section 13 of the Act, the Committee reports must be kept on file for at least 3 years at the facility and must be available for inspection by APHIS and any funding Federal agency (7 U.S.C. 2143(b)(4)(B)). It is necessary for APHIS inspectors to be able to copy reports to obtain documentation of noncompliance and to conduct investigations of possible noncompliance. These are the occasions when inspectors would need to copy the Committee reports. The requirement remains as initially proposed.

We received 307 comments (282 from the research community and 25 from members of the general public) stating that the Committee should not be required to monitor projects on an ongoing basis to assess deviations from originally approved protocols [ACUPs], as required by the assurance statement that is part of the Committee's report under proposed § 2.35(b)(2)(i)(D). This requirement is mandated by section 13(b)(4)(A) of the Act. It requires that the Committee's report include "any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, * * *" (7 U.S.C. 2143(b)(4)(A)). Ongoing practices and procedures must necessarily be reviewed in order to comply with this requirement. No change is made in the revised rule based upon this comment.

We received 321 comments (296 from the research community and 25 from members of the general public) objecting to the assurance statement required in proposed § 2.35(b)(2)(i)(D) on the grounds that it is too complicated. We have simplified the assurance by using the term "ACUP" in place of "research protocols, procedures, and practices" as originally proposed, since this term encompasses the areas of concern to the Committee in reviewing painful procedures. Also, as explained above, the instruction to cease using methods and procedures that are not in compliance with the approved ACUP must come from the research facility because the CEO or responsible institutional institutional official must certify compliance with the Act, regulations, and standards on the facility's annual report, and must report any deviations from the regulations. The Committee can be required only to provide assurance regarding matters of which it has first-hand knowledge. Accordingly, paragraph (b)(2)(i)(D)(3) is revised to require assurance that the Committee has notified the CEO or responsible institutional official of the research facility to instruct the investigator to cease using the noncomplying methods and procedures.

We received 527 comments (502 from the research community and 25 from members of the general public) stating that research facilities should be allowed more than 30 days to correct deficiencies found in the course of Committee inspections. We received 149 comments suggesting a means of requesting an extension in the event that a deficiency cannot be corrected within 30 days for justifiable reasons, such as if more time is required to purchase new primary enclosures or to repair the physical plant. We do not agree with the commenters' suggestion that the regulations should provide a formal means of requesting an extension of time to correct deficiencies. Rather, APHIS will continue to consider non-compliance matters on a case-by-case basis, as it has in the past.

Two commenters requested clarification of the requirement contained in proposed § 2.35(b)(2)(ii) for reporting deficiencies to the Deputy Administrator. As previously explained, the reference to the Deputy Administrator is changed to the Administrator. We have revised the notification procedure to reflect the fact that the facility is ultimately responsible for compliance with the Act and regulations, and that the CEO or responsible insitutitional official must certify the facility's compliance in the annual report. Accordingly, § 2.35(b)(2)(ii) is revised to require that the Committee notify the CEO of the research facility or the official responsible for animal care if the CEO has delegated authority to that official, as well as the administrative unit representative, of any deficiencies found, including noncompliance with an approved ACUP involving a painful procedure. This notification must be done, in writing, within one business day of discovery. The Committee must also provide a copy of its inspection certification report citing a deficiency to the CEO or the institutional official responsible for animal care, and to the administrative unit representative. The facility then has 30 days to correct the deficiency. If it remains uncorrected 30 days after notification of the CEO or other responsible institutional official, the Committee must notify the Administrator and any funding Federal agency of the uncorrected deficiency in accordance with section 13(b)(4)(C) of the Act (7 U.S.C. 2143(b)(4)(C)). We are requiring that this must be done within 5 days of completion of the 30-day correction period to avoid further delay. The Committee must provide a copy of

its inspection certification report and a copy of its written notification of deficiency to the Administrator. The Committee must also file a copy of its inspection certification report and written notification of deficiencies at the central repository maintained by the facility in accordance with § 2.30(m) for all reports required in this Subchapter so that they are available to APHIS officials and inspector(s), and to any funding Federal agency. The proposed rule erroneously referred to the "administrative representative" and not to the "administrative unit representative" as intended. Section 2.35(b)(2)(ii) of the revised rule reflects these changes.

We did not receive any comments addressing proposed § 2.35(b)(2)(iv), which requires that reports remain on file for at least 3 years at the research facility and be available for inspection and review by APHIS inspectors and any funding Federal agency. This requirement is set forth in § 2.30(m) of this rule, and it is revised to require that, upon notification from the Administrator, research facilities must also retain records pending completion of an investigation or proceeding under the Act, and until their disposition is authorized by the Administrator.

4. *Reviews.* Following the reorganization of §§ 2.30 and 2.35, and the reassignment of duties and responsibilities so that only statutorily mandated duties are imposed on the Committee, and the revisions to Subpart C described above, the remaining reviewing functions of the Committee under the proposed rule would be as follows:

(i) No research, testing, or teaching involving [ACUPs] falling under Categories 3 and 4 in this paragraph performed by a facility's personnel at any location shall commence prior to approval by the Committee [of the ACUP]. Prior to granting approval, the Committee shall ensure that [ACUPs] in any of the categories listed [in the Categories of Animal Use in Research and Testing] contain provisions for acceptable and proper animal care, treatment, practices, methods, and use of pain-relieving drugs. (Proposed § 2.35(b)(3)(ii)).

(ii) The Committee shall approve an [ACUP] only when animal pain, distress, and functional or sensory impairment are minimized; all survival surgery is performed using aseptic procedures; adequate veterinary care is planned for and provided; multiple use of such animal(s) is justified for the purpose of conserving an endangered species or marine mammals or as an essential related component of a particular project or [ACUP]; and the appropriate use of anesthetics, analgesics, tranquilizing drugs, or euthanasia, when necessary, and that the use of such drugs is in accordance with established or accepted veterinary medical procedures and usage. The use of such drugs shall be in accordance with the instructions of the attending veterinarian.

(Proposed § 2.35(b)(3)(iii)).

As previously discussed under the heading "§ 2.30(d)," we have determined that the Committee must review and approve all ACUPs before any research, testing, or teaching involving animals can commence, and § 2.35(b)(3)(i) of this revised rule (formerly proposed § 2.35(b)(3)(ii)) is revised accordingly. Requiring review of all ACUPs, not just those involving painful procedures, is consistent with PHS Policy and avoids the need for determining the degree of pain or distress that can reasonably be anticipated to result from a proposed procedure.

We had originally proposed that "no research, testing, or teaching involving protocols falling under Categories 3 and 4 of the Categories of Animal Use in Research and Teaching performed by a facility's personnel at any location shall commence prior to approval by the Committee." (Proposed § 2.35(b)(3)(ii)). Using the "Categories of Animal Use in Research and Testing" was proposed as a means of classifying animal procedures into 4 categories, ranging from those involving little or no pain or distress to those involving severe or unrelieved pain or distress. The Committee would be required to review the ACUPs for procedures falling in the categories involving higher degrees of pain, Categories 3 and 4, to ensure that they contained provisions for acceptable and proper animal care, treatment, practices, methods, and use of pain relieving drugs. Examples of the types of procedures typically falling into the different categories were provided in the proposed Categories of Animal Use.

We received numerous and varied comments regarding the proposed Categories, ranging from general approval and suggestions that the proposed categories be incorporated into the Annual Report (VS Form 18–23) (12 commenters) to disapproval and suggestions that they be deleted because the commenters found them confusing and/or inappropriate (77 commenters). Four commenters recommended that the proposed categories be revised to include additional detail, including further categorization and definition.

It became clear from our review of the comments that a fair number of the commenters were misconstruing the proposed examples as fixed categorizations of procedures into the 4 proposed categories. This was certainly not our intent in providing the examples. As stated in the supplementary information accompanying the proposed rule at 52 FR 10302, "[t]hese [Categories of Animal Use in Research and Teaching] are for the guidance of the investigator in planning the research protocol [ACUP] and for the Committee in determining the level of pain or distress to be allowed and the necessity of such pain or distress when approving the protocol [ACUP] * * *. The list of examples is not all inclusive but is provided as guidance for where a particular protocol [ACUP] might be classified in relation to the pain or distress involved."

Despite this explanation of the examples provided for each category, we received 72 comments objecting to all toxicity studies being classified as Category 3. Toxicity studies were included as an example of the type of procedure which would typically but not necessarily fall under Category 3 as involving "significant but unavoidable pain or distress to the animals." A toxicity study which did not involve this level of pain or distress would not be in Category 3 under the proposed rule.

Other comments addressing the proposed Categories of Animal Use included one from a member of the general public suggesting that a fifth category for "severe pain" be included, and one from a member of the research community generally approving of the proposed categories.

The proposed Categories of Animal Use was selected from among several like categorizations and was developed by the Scientists Center for Animal Welfare. This categorization was the result of many conferences and seminars addressing the issue of how to classify procedures involving differing levels of pain and is currently in use in 20 or more research facilities. As a result of the comments received, we have considered a number of alternatives for addressing the concerns raised by the commenters. One alternative considered was using a different categorization system. It is likely, however, that similar issues would be raised in response to any proposed categorization of types of procedures. We also considered proposing additional examples of the types of procedures that would typically fall into the different categories, in response to the comments requesting additional definition and categorization, however these too could be misconstrued as fixed categorizations rather than as examples provided for guidance. We next considered removing the examples from the rule to avoid any misconception as to whether they were actually fixed categorizations. This would likely raise concerns that the

regulations did not provide sufficient guidance and would leave facilities subject to challenge if they did not require their Committees to review procedures regarded by the Department as involving significant pain or distress.

Having carefully considered the comments and the various alternatives summarized above, we have determined to remove the Categories of Animal Use in Research and Teaching and to require Committee review and approval of all procedures involving warm-blooded animals covered by the Act. As stated above, we believe that it is necessary that the Committee review all ACUPs to enable research facilities to provide assurance that their facilities are in compliance with the Act, regulations, and standards. Without this review, the CEO or institutional official with responsibility for animal care could not, in good faith, certify the facility's compliance in its annual report. This requirement will avoid subjective determinations as to how to categorize pain or distress and challenges to those determinations after the procedures in question have been undertaken. This approach is consistent with PHS Policy and similar practices already exist at many of the institutions responsible for complying with these regulations. Accordingly, the requirement for Committee review and approval of all ACUPs will not disrupt the practices employed at many research facilities.

We are also revising the rule to relieve the burden this requirement will impose upon the Committee by incorporating, in part, the practice authorized by the PHS Policy for assigning ACUPs to individual members of the Committee for preliminary review, unless a Committee member requests in-depth review by a quorum of the Committee. Under the revised rule, the reviewing member of the Committee is responsible for reviewing an assigned ACUP and for advising the principal investigator if modification is needed in order to obtain the necessary Committee approval. The Committee member must present his or her findings to a quorum of the Committee for formal action and must recommend approval or disapproval of the ACUP. A quorum of the Committee must approve the ACUP before the proposed research, testing, or teaching can proceed. One commenter noted that the PHS Policy allows an individual Committee member to approve a proposed research project. We are requiring Committee approval of ACUPs in accordance with the section 13(b)(2) of the Act which requires a quorum for all formal actions of the Committee (7 U.S.C. 2143(b)(2)).

One member of the general public commented that unanimous approval by the Committee should be required for all protocols [ACUPs]. This is contrary to the Act, which requires a quorum for all formal actions of the Committee (7 U.S.C. 2143(b)(2)). "Quorum" is defined by the Act as a majority of the Committee members (7 U.S.C. 2132(m)). No change is made in the revised rule based upon this comment.

Also, in accordance with PHS Policy, we are providing a mechanism to enable the Committee to require that an approved practice or procedure be suspended, in accordance with proposed and revised § 2.35(b)(2)(i)(D), if it determines that a procedure or practice is not being performed in accordance with the approved ACUP. We are providing that the Committee can do so by withdrawing or suspending its approval of an ACUP. Section 2.30(d) requires Committee approval for all ACUPs before they commence, and section 13(a)(3)(E) of the Act requires that any exceptions to the standards be specified in the ACUP and explained in a report filed with the Committee (7 U.S.C. 2143(a)(3)(E)). Accordingly, once Committee approval is withdrawn, the procedure or practice must cease or the research facility is in violation of the regulations. Section 2.35(b)(3)(i) of the revised rule is changed to provide that no research, testing, or teaching involving warm-blooded animals covered by the Act shall continue if the Committee suspends its approval.

Eight commenters from the general public urged that painful experiments should not be allowed at all. One of the stated purposes of the 1985 amendments to the Act is to minimize animal pain and distress (7 U.S.C. 2143(b)(3)). The Act is clear, however, in its direction that except as provided in section 13(a)(6) of the Act, it does not authorize the Secretary to promulgate regulations "with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such facility; * * *" (7 U.S.C. 2143(a)(6)(A)(i)) and the Department therefore does not have the authority to prohibit all painful experiments.

Three commenters from the general public suggested that in determining whether to approve a proposed ACUP, the Committee should compare the public gain which would result from the research versus the pain inflicted on the animal. Although the Act does not direct the Committee to make this judgment, it does direct the Committee to ensure compliance with the Act to "minimize pain and distress to animals" and to inspect research facilities for compliance with the Act, regulations, and standards (7 U.S.C. 2143(b)(3)). One of the stated findings of Congress set forth in the Act is that "measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of federal funds" and "measures which help meet the public concern for laboratory animal care and treatment are important in assuring that research will continue to progress." (7 U.S.C. 2131). Proposed § 2.35(b)(3)(iii) provides the bases upon which the Committee will approve or disapprove a proposed ACUP. The bases enumerated include provision for the commenters' concerns. We further believe that the provision for a nonaffiliated member of the Committee who is "intended to provide representation for general community interests in proper care and treatment of animals" (7 U.S.C. 2143(b)(1)(B)(iii)) will bring these considerations to bear in Committee deliberations, and that the Committee as a whole will keep the purposes of the Act in mind in performing its duties. No change is made based upon this comment and it is redesignated as § 2.35(b)(3)(ii) in the revised rule.

Two commenters stated that the language in proposed § 2.35(b)(3)(iii) should be changed from "The Committee shall approve such protocols only when * * *" to "The Committee shall approve procedures only when * * *." We have revised this paragraph by replacing the term "protocol" with "ACUP."

We are also numbering the conditions listed in proposed § 2.35(b)(3)(iii) in the revised rule which must be satisfied for the Committee to approve an ACUP, and are correcting the typographical and grammatical errors that appeared in it.

We received 478 comments from members of the general public in regard to proposed § 2.35(b)(3)(ii) concerning the need for stronger and stricter requirements for reporting painful procedures and use of pain relieving drugs, and for better identifying those procedures not involving pain, procedures involving unrelieved pain, and procedures involving pain relieved with drugs. We have addressed these comments separately from those concerning the proposed Categories of Animal Use because they more properly concern the research facility's annual report, VS Form 18–23 than proposed § 2.35(b)(3)(ii). The annual report requires an accounting of the number of animals utilized in procedures involving no pain, unrelieved pain, and relieved pain. We are aware of instances where

animals are reported under Column 'C', "no pain" because the pain is relieved with drugs. This is improper because the relief of pain does not make the procedure one which does not involve pain. As noted previously, 12 commenters felt that the proposed Categories of Animal Use should be used on VS Form 18–23, instead of the current designations.

We believe that the combination of Committee review of all ACUPs, requiring Committee approval of all proposed ACUPs before they can commence, Committee inspections, and the research facility's responsibility to assure that pain and distress are minimized will result in more accurate reporting of painful procedures. The annual report, VS Form 18–23 will also be clarified to require that painful procedures be reported as such, regardless of whether or not pain is relieved.

We received 40 comments stating that "Committee" should appear in § 2.35(b)(3) of the final rule in place of "attending veterinarian" wherever the phrase "in accordance with the instructions of the attending veterinarian" appears. The phrase appears in proposed § 2.35(b)(3)(iii) only in regard to the use of pain relieving drugs. The requirements in the remaining paragraphs of proposed § 2.35(b)(3) are incorporated in § 2.30 of the revised rule because they are the responsibility of the research facility. Procedures and practices which must be done in accordance with the instructions of the attending veterinarian, as provided in proposed § 2.35(b)(3), are those which pertain to providing proper veterinary care, and providing for animal health and well-being, such as the proper use of drugs and pre- and post-procedural care. As explained previously, adequate veterinary care must be provided in all research procedures and is not limited to those involving surgery. Section 2.35(b)(3) of this rule is revised accordingly. These are areas within the expertise of the attending veterinarian, as opposed to the Committee, and remain subject to the instructions of the attending veterinarian in the revised rule.

Subpart D—Attending Veterinarian and Adequate Veterinary Care Introduction

As explained above under the heading, "Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities" and under the subheading, "Reorganization of §§ 2.30 and 2.35," in this revised rule we are reassigning responsibility to the research facilities for certain duties that had been placed upon the attending veterinarian in the proposed rule. These changes are made in response to the concerns raised by 480 commenters (455 from the research community and 25 from members of the general public) who stated that as proposed, § 2.40(e) would place the attending veterinarian in the position of enforcement agent for the Department. These changes should also allay the concerns of the four commenters from the research community who stated that the Committee was improperly given veterinary responsibilities in § 2.35 of the proposed rule.

With this reorganization of §§ 2.30, 2.35, and 2.40, and the reassignment of responsibilities, we believe that the research facility, the Committee, and the attending veterinarian will serve as an effective built-in institutional quality assurance mechanism. The Act requires standards for adequate veterinary care, and consultation with a veterinarian in the planning of any painful procedure. The regulations in this revised rule are intended to ensure proper planning and conduct of research procedures and adequate veterinary care.

Although ultimate responsibility for many of the responsibilities originally placed on the Committee and the attending veterinarian in the proposed rule is placed on the research facility in the revised rule, many of these responsibilities must still be performed under the guidance or supervision of the attending veterinarian or in consultation with the attending veterinarian because they fall within his or her expertise. Accordingly, § 2.30 of this rule has been revised to require each research facility using or holding animals for research, testing, or teaching to establish, maintain, and abide by a written program of adequate veterinary care in accordance with § 2.40. (A research facility may or may not include the written program of adequate veterinary care in its standard operating procedure (SOP) if it employs a full-time attending veterinarian.)

In Subpart D, paragraph (e) of proposed § 2.40, "Research facilities," is most affected by the reassignment of responsibility. For example, proposed § 2.40(e)(2) would have required the attending veterinarian to provide consultation and guidance in areas of veterinary care. In the revised rule, it is the research facility's responsibility to require and ensure that the attending veterinarian performs those functions.

General. Proposed § 2.40 would require a written program of adequate veterinary care between a dealer, exhibitor, or research facility, and its attending veterinarian, which includes a program for disease control and prevention, pest and parasite control, pre- and post-procedural or surgical care, nutrition, euthanasia, proper and appropriate use of anesthetics, analgesics, tranquilizers, and any other pain relieving drugs.

We received comments addressing the nature of the program of adequate veterinary care generally, and the frequency of program review by the Area Veterinarian in Charge that should be required when there is a part-time as opposed to a full-time attending veterinarian. These areas of commenters' concern are clarified in the revised rule and are discussed below.

We received 10 comments (8 from the research community and 2 from dealers) generally in favor of strengthening the current regulations concerning veterinary care and 35 comments (27 from dealers and 8 from exhibitors) generally opposed to strengthening the requirements. We have determined, based upon our experience, and for the reasons provided in the supplementary information to the proposed rule, published in the **Federal Register**, March 31, 1987, (*see* 52 FR at 10303), that enhanced requirements for adequate veterinary care are necessary to promote the health and well-being of animals.

We received 329 comments (304 from the research community and 25 from the general public) expressing concern that the tone of proposed Subpart D is negative and will create a confrontational relationship between attending veterinarians and research personnel and/or Committee members, rather than a cooperative relationship. We believe that the reorganization of §§ 2.30, 2.35, and 2.40 in the revised rule should allay this concern, because it resolves any disputes over areas of expertise and responsibility. With the reassignment of the areas of responsibility of the research facilities, Committee members, and attending veterinarians in this revised rule, we believe the regulations will result in a synergistic relationship which fosters animal welfare.

Attending veterinarian. Proposed § 2.40(a) would require each licensee or registrant to have an attending veterinarian who is "accredited" by the U.S. Department of Agriculture in accordance with regulations issued by the Secretary under the Act. The attending veterinarian would be responsible for providing adequate veterinary care to the animals in accordance with the written program of adequate veterinary care required in

proposed paragraphs (b) and (c) of § 2.40.

We received numerous comments from the research community addressing "accreditation" of the attending veterinarian. Forty-six commenters from the research community objected that proposed § 2.40(a) is unacceptable without the details of "accreditation" being included; 507 commenters (482 from the research community and 25 members of the general public) stated a more general concern that the process for "accrediting" veterinarians was not explained in the proposed rule. One hundred commenters from the research community stated that APHIS is not in a position to establish professional qualifications for "accreditation" of attending veterinarians.

As previously explained in this supplementary information, and under the heading, "Attending veterinarian," in a related document, Part 1—"Definition of Terms," published elsewhere in this issue of the **Federal Register**, docket no. 88–013, we are removing references to "accreditation" from the regulations pending the Department's renaming and development of standards for the "accreditation" program. Proposed standards will be published separately at a later date in a proposed rule. We believe that this action will satisfy the commenters' concerns.

Program of adequate veterinary care. Proposed § 2.40(b) would require the attending veterinarian to establish, maintain, and supervise programs of disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, euthanasia, and adequate veterinary care for all animals on the premises of the dealer, exhibitor, or research facility. The programs must also include the proper and appropriate use of anesthetics, analgesics, tranquilizers, and euthanasia, when indicated. The reader should note that the requirement for a program of pre- and post-procedural care in proposed § 2.40(b) applies to all research procedures and processes involving animals and is not limited to surgical procedures. Accordingly, we have revised all of the provisions of § 2.40 in this rule to refer to pre- and post-procedural care in place of pre- and post-surgical care wherever it appears.

In addition to the comments objecting to the allocation of responsibilities among the facilities, the Committee, and the attending veterinarian, we also received 64 comments from members of the research community stating that the establishment, maintenance, and supervision of a program of adequate veterinary care in research facilities should be the responsibility of the Committee, and not the attending veterinarian. We do not agree that this responsibility should be imposed on the Committee. The Act does not require the Committee to develop a program of adequate veterinary care. Moreover, only one member of the Committee, the attending veterinarian, would be certain to have the requisite expertise to do so. As previously explained under the discussion of Subpart C, we have determined that responsibilities not imposed by the Act on the Committee should be placed on the facility.

Establishment and maintenance of the program of adequate veterinary care is the responsibility of the facility, as provided in § 2.30 of the revised rule. Accordingly, proposed § 2.40(b) is revised to state that responsibility for establishing and maintaining a program for adequate veterinary care is on the dealer, exhibitor, and research facility, instead of the attending veterinarian. The program would remain under the supervision and control of the attending veterinarian, however, because of the attending veterinarian's expertise. We have also clarified paragraph (b), to provide that programs for disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, the proper and appropriate use of anesthetics, analgesics, tranquilizers, and euthanasia when indicated, are all elements of a program of adequate veterinary care and must be included by a dealer, exhibitor, and research facility in order to have a comprehensive program as intended by the Act.

Two commenters from the research community stated that the Department should promulgate regulations on what constitutes an adequate program of veterinary care. The elements that must be included in a program of adequate veterinary care are provided in § 2.40(b) of the revised rule. They are programs for disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, euthanasia, and the appropriate use of pain relieving drugs. It is the responsibility of the dealer, exhibitor, or research facility to ensure that its program of veterinary care adequately covers those areas. We are also revising § 2.40(c) to require that these areas be included in the written program for adequate veterinary care. In addition, § 2.40(d) of this revised rule requires daily observation of each animal in order to administer properly the program of adequate veterinary care. The clarification of these paragraphs in the revised rule to specify the elements that comprise a program of adequate veterinary care should satisfy the commenters' concern.

Three exhibitors commented that a responsible official of the dealer, exhibitor, and research facility should coordinate with the attending veterinarian in developing a program of adequate veterinary care. We believe that the concerns raised by this comment have been addressed in the revised rule, which requires dealers, exhibitors, and research facilities to establish and maintain the program of veterinary care and requires the program to be under the control and supervision of the attending veterinarian. The suggested coordination will result from this requirement, if properly implemented.

We received 25 comments from members of the research community stating that veterinarians are not trained for the role of determining what anesthesia and analgesics to provide. We believe the attending veterinarian has this expertise and is best suited to provide guidance concerning the proper use of pain relieving drugs and the need for them. One commenter stated that requiring the principal investigator to provide anesthesia and analgesics in accordance with the attending veterinarian's recommendation places the attending veterinarian in the position of deciding critical experimental issues, and this is not the role for which the attending veterinarian is trained. We disagree with the commenters. Under proposed § 2.40(e)(2)(i), the attending veterinarian is required to provide consultation and guidance to the principal investigator and to laboratory personnel during both planning and development of the ACUP and during the performance of the actual research. The principal investigator can consult with the attending veterinarian regarding the special needs and requirements of the research and experimental design, and together they can resolve outstanding matters concerning the use of pain relieving drugs. Additional review of determinations regarding the use of drugs is provided under § 2.35. Under that section, the ACUP must be reviewed and approved by the Committee, and the principal investigator must explain why an exception to the requirement to provide for the use of pain relieving drugs is justified. We do not believe that the attending veterinarian will be in the position of deciding critical experimental issues that are outside the scope of his or her expertise or duties.

We received 10 comments (3 from dealers and 7 from exhibitors) stating

that the attending veterinarian should not have to be present for routine health care procedures, such as vaccinations and worming. We agree with the commenters. For this reason, there was no proposed requirement that the attending veterinarian be present at all times for those procedures, nor is there one in the revised rule. The requirement is that the program of adequate veterinary care, including the procedures involved in administering a program of adequate veterinary care, be conducted under the supervision and control of the attending veterinarian. This does not require the attending veterinarian's presence at all times. No change is made in the revised rule based upon this comment.

Proposed § 2.40(c) would require that a written program of adequate veterinary care between the dealer, exhibitor, or research facility and the "Doctor of Veterinary Medicine" be drawn up and reviewed annually by APHIS. It would also require that the program provide for regularly scheduled visits by the veterinarian as appropriate to the facility's needs, if a part-time or consulting veterinarian is the attending veterinarian. Each dealer, exhibitor, and research facility would be required to keep a copy of the program on file on the premises and to provide a copy to the Area Veterinarian in Charge annually. Proposed paragraph (c) would also provide minimum requirements that must be included in the written program of adequate veterinary care, in addition to the areas of care provided in paragraph (b).

Six commenters from the research community stated that the term "attending veterinarian" should appear in place of "Doctor of Veterinary Medicine." We agree and have made this change in the revised rule. We intended specifically that the attending veterinarian, not any "Doctor of Veterinary Medicine," be involved in the development of the program of veterinary care. We have revised paragraph (c) accordingly.

We received 315 comments (290 from members of the research community and 25 members of the general public) stating that the written program of adequate veterinary care required in proposed § 2.40(c) reads like a contract between the facility and a part-time or consulting attending veterinarian and therefore would not be appropriate for full-time or staff attending veterinarians. Representatives of HHS suggested that institutions with a full-time attending veterinarian on staff should not be required to prepare and submit annually for review a separate program document, since they would have a program of adequate veterinary care in place through established positions, lines of authority, and standard operating procedures. We agree in part with the HHS suggestion. We believe that if a dealer, exhibitor, or research facility has established a written program of adequate veterinary care, separately or as part of its standard operating procedure, and has a full-time attending veterinarian on staff, it need not annually prepare and submit to APHIS a separate document for the program of adequate veterinary care. This is because the written program or SOP, coupled with the established lines of authority and responsibility, would address the requirement for maintaining a program of adequate veterinary care. We also agree that if a dealer, exhibitor, or research facility has a written program of adequate veterinary care and a full-time attending veterinarian on staff, it is sufficient if the written program of adequate veterinary care is reviewed by APHIS inspectors in the course of their regular duties, on the premises, rather than requiring the dealer, exhibitor, or research facility to redraft and submit a copy of their program annually to the Area Veterinarian in Charge, Dealers, exhibitors, and research facilities that have a full-time attending veterinarian on staff generally are less likely to change their attending veterinarian than are those with a part-time or consulting attending veterinarian, and therefore changes to the program of adequate veterinary care due to changes in personnel are less likely. Additionally, full-time staff attending veterinarians can make daily personal observations or receive reports on animal conditions and care from employees under their supervision, and are in a position to respond promptly to veterinary care needs with trained personnel. Part-time or consulting attending veterinarians would not have the same opportunity to observe and to act.

We are requiring in the revised rule that if a dealer, exhibitor, or research facility utilizes the services of a part-time or consulting attending veterinarian, it must provide the Area Veterinarian in Charge with its written program of adequate veterinary care, prepared and signed by its attending veterinarian, on an annual basis. We are requiring that a part-time or consulting attending veterinarian prepare and sign the written program of adequate veterinary care annually in order to verify that it is the current program of veterinary care being implemented by the attending veterinarian and the dealer, exhibitor, or research facility. The dealer, exhibitor, or research facility must also keep a copy of the program on file at its premises at all times. We are revising § 2.40(c) in this rule to clarify these differences for dealers, exhibitors, or research facilities that have a full-time attending veterinarian on staff and those that utilize the services of a part-time or consulting attending veterinarian. They appear in paragraphs (c) (1) and (2) of § 2.40 in the revised rule.

Thirty-seven commenters (36 from the research community and 1 exhibitor) stated that the program of veterinary care should be reviewed every 3 years, instead of annually, to coincide with registration renewal. We are retaining the requirement for annual review. The need for adequate veterinary care has nothing to do with registration renewal every 3 years. Rather, it is concerned with the daily health needs of the animals. The commenters do not mention the fact that the requirement for annual review of the program of veterinary care also applies to dealers and exhibitors We believe that annual review is desirable in any event, because of changes in the technology of veterinary care delivery, and changes in accepted procedures.

Four dealers commented that visits by a part-time or consulting attending veterinarian should not be required to be by appointment, but should only be required to be made on a routine basis. Proposed § 2.40(c) requires "regularly scheduled visits appropriate to the facility's needs." There is no requirement for visits by appointment. Our concern is that visits be sufficiently frequent to provide adequate veterinary care, as "appropriate to the facility's needs." No change is made to this provision in the revised rule.

We have made one additional change to proposed paragraph (c). In providing the minimum requirements that must be included in the written program of adequate veterinary care, we omitted reference to the areas of veterinary care that must be included. These are the areas of veterinary care identified in § 2.40(b) of both the proposed and the revised rules. This reference is added as new paragraph (c)(3) and proposed paragraphs (c) (1) through (6) are redesignated as (c)(3) (i), (ii), and (iv) through (vii) in the revised rule. This change also responds to the 2 comments we received from members of the research community who stated that regulations should be provided on what determines adequate veterinary care.

Observation of animals and care for sick, diseased, injured, lame, or blind

animals. Proposed § 2.40(d) would require daily observation of animals by the dealer, exhibitor, veterinarian, animal caretaker in charge, or someone under their direct supervision. In drafting proposed § 2.40(d), we inadvertently omitted research facilities from the entities required to observe each animal daily. We believe this subsection was understood to apply to research facilities since the second sentence refers to animals obtained for research purposes. Also, proposed § 2.40(e)(2) imposes requirements on the attending veterinarian of a research facility in addition to those contained in paragraphs (a) through (d). The term "research facility" is added following "exhibitor" in the revised rule. The term "veterinarian" was intended to refer to an attending veterinarian, and is modified in the revised rule accordingly.

We received two comments from the research community stating that provision should also be included for observation of the animals by the principal investigator. We agree with this comment since the investigator is qualified to perform the required observation. The revised rule is changed to include observation by the investigator.

One exhibitor and 1 member of the research community commented that the requirement for daily observation of the animals is excessive. One commenter noted that it is impractical to require the veterinarian of a large facility, such as large exhibition facilities or game farms, to observe each animal daily, and that observation might actually be detrimental to the proper management of some species, such as bears isolated for cubbing. We disagree with the commenter. The requirement for daily observation of most species has been part of the regulations since 1967 without resultant problems. It is also consistent with the NIH Guide for the Care and Use of Laboratory Animals, which states that "[a]nimals should be observed and cared for by qualified personnel every day, including weekends and holidays, * * *" (p. 28). Daily observation is a necessary part of good husbandry practices. It is extremely important that this requirement be retained in order to detect possible problems, including detection of disease and abnormal behavior. Also, it is not necessary that one individual observe all the animals. The proposed regulation would require daily observation by "the dealer, exhibitor, [research facility], [attending] veterinarian, [principal investigator], or animal caretaker in charge, or someone under their direct supervision." (Bracketed terms are added to the regulation in the revised rule.) We are clarifying this provision in the revised rule to provide that someone under the direct supervision of the attending veterinarian, principal investigator, or animal caretaker in charge would be allowed to perform the required observation if he or she is required to report promptly his or her findings to trained personnel and veterinary care is promptly provided. In this manner, the need to provide necessary veterinary care will be promptly identified and communicated to responsible and trained personnel. We do not believe that objections to the requirement are valid. The requirement is retained in the revised rule.

Proposed § 2.40(d) would also require that "each facility provide veterinary care or humanely dispose of sick, diseased, injured, lame, or blind animals, unless this would be inconsistent with the research purposes for which the animal was obtained and is being held * * *." It would also require compliance with any state or local law requiring holding of animals suspected of being diseased for a specified period of time.

We received 31 comments from the research community proposing that the term "unhealthy" be substituted for "sick, diseased, injured, lame or blind" in proposed § 2.40(d). We disagree with the commenters since an animal can be lame or blind and still be considered "healthy." Substitution of "unhealthy" will not cover all of the conditions listed in the proposed regulation. The substance of the requirement, to provide veterinary care or to humanely dispose of animals that are "sick, diseased, injured, lame, or blind," has been included in the regulations since 1967 and has not presented any problems to our knowledge. Reference to "sick, diseased, injured, lame, or blind," animals will remain in the revised rule. We are revising the provision of the proposed rule requiring "[t]he facility" to provide veterinary care or humanely dispose of sick, diseased, injured, lame, or blind animals. It is revised to clarify that this requirement applies to all research facilities, dealers, and exhibitors.

Research facilities. Proposed § 2.40(e) would impose additional requirements on the attending veterinarian of a research facility. It would require the attending veterinarian to be a member of the Institutional Animal Care and Use Committee and provide that he or she has "authority to enter all animal rooms, sites, facilities, and animal use areas, at any time."

The requirements imposed on the attending veterinarian of a research facility in the proposed rule include providing consultation and guidance to principal investigators and laboratory personnel during planning and development of an ACUP, and during actual research, whenever a procedure is likely to produce pain or distress in an animal. Proposed paragraphs (A) through (D) of § 2.40(e)(2)(i) identify specific areas in which the attending veterinarian must provide consultation and guidance. Proposed § 2.40(e)(2)(ii) would require the attending veterinarian to establish a recordkeeping system and a standard operating procedure which indicates and assures the proper use of drugs and proper pre- and post-surgical care on a daily basis. Proposed § 2.40(e)(2)(iii) would require the attending veterinarian to sign an assurance statement on the research facility's annual report, VS Form 18–23, certifying that he or she has authority to enter all animal areas, that he or she has carried out the requirements of § 2.40, and that he or she has read and understands the regulations and standards contained in Parts 2 and 3 of the Animal Welfare regulations.

In the revised rule, § 2.40(e)(1), the research facility is directed to require that the attending veterinarian be a member of the Committee. Similarly, it is the research facility's responsibility, under § 2.40(e)(2)(i), to require the attending veterinarian to provide the requisite consultation and guidance. Also, as discussed in this supplementary information under the heading, "Subpart B—Registration," only the chief executive officer or the institutional official with responsibility for animal care will be required to sign the facility's annual report. This is consistent with the PHS Policy. Accordingly, paragraph (iii) is deleted from § 2.40(e)(2) in the revised rule.

Many of the comments we received addressing proposed § 2.40(e) were from members of the research community. Therefore, unless otherwise indicated, the source of the comments discussed in this section is the research community.

Ten commenters stated that the word "all" should be deleted from paragraphs (e)(1) ("The attending veterinarian shall have * * * authority to enter all animals rooms, sites, facilities, and animal use areas, at any time"), (e)(2)(i)(D) (the attending veterinarian shall provide consultation and guidance in "[e]valuation and approval of all animal surgical areas"), and (e)(2)(iii)(A) (attending veterinarian shall sign an assurance statement on the facility's annual report certifying that he or she

has "authority to enter all animal areas"). Proposed § 2.40(e)(2)(iii) is removed from the revised rule since the attending veterinarian is not required to sign the annual report. The other references to "all" remain as proposed, because we believe it is essential that all animal rooms and animal areas be accessible to the attending veterinarian to assure proper and adequate veterinary care and to carry out the intent of the Act. The requirements that the attending veterinarian provide consultation and guidance in the areas of evaluation and approval of all animal surgical areas and qualifications of personnel involved with animal surgery are ultimately the responsibility of the facility and are included in § 2.30 in the revised rule. The facility must assure, however, that evaluation and approval of all animal surgical areas and qualifications of personnel are done in accordance with instructions of the attending veterinarian. Accordingly, § 2.40(e)(2)(i)(D) of the revised rule retains the requirement that the research facility require the attending veterinarian to provide consultation and guidance with respect to evaluation and approval of all animal surgical areas and qualifications of personnel involved with animal surgery.

Fifteen commenters stated that the attending veterinarian should be allowed access to enter animal rooms, sites, facilities, and animal use areas only "at any reasonable time," rather than "at any time" as proposed in § 2.40(e)(1). The commenters expressed concern that entry by the attending veterinarian in an animal study area during a procedure could be disruptive. We have determined that access "at any time" is imperative to prevent obstruction by those principal investigators for whom there is never a "reasonable" time to allow entry by the attending veterinarian. It is desirable that the attending veterinarian consult with the investigator to determine what would be a reasonable time and that the attending veterinarian be able to examine the ACUP in making this determination so as not to disrupt procedures or a controlled research environment. This may be done as part of the consultation and guidance provided during ACUP planning and development, and during actual research. Moreover, as previously discussed in the discussion of § 2.30(b) under the heading, "§ 2.30 Additional requirements for research facilities," research facilities could establish guidelines in the facility's written policies and procedures to help reassure personnel that this right of access would be exercised in good faith. It is important, however, that the attending veterinarian retain the right to have access at any time to ensure compliance with the program of adequate veterinary care, for the benefit of the animal.

Forty-four commenters stated that the requirements imposed on the attending veterinarian in proposed § 2.40(e)(2) properly belong to the Committee. We do not agree. The Act requires that the principal investigator consult with a doctor of veterinary medicine in the planning of any procedure likely to produce pain or distress in an experimental animal (7 U.S.C. 2143(a)(3)(C)). The areas listed in proposed paragraphs (A) through (D) of § 2.40(e)(2)(i) are necessary components of research planning and development and of veterinary care.

Proposed § 2.40(e)(2) states that:

> In addition to the requirements set forth in paragraphs (a) through (d) of this section, the attending veterinarian of a research facility shall:
>
> (i) provide consultation and guidance to principal investigators and other laboratory personnel during protocol [ACUP] planning and development, and during actual research, whenever any procedure is likely to produce pain or distress in an animal. Such consultation and guidance shall include at least the following areas:
>
> (A) the proper use of tranquilizers, analgesics, anesthetics, and euthanasia according to the accepted, or common veterinary practice procedures;
>
> (B) provision for adequate pre-surgical and post-surgical care by laboratory workers in accordance with current established veterinary medical and nursing procedures;
>
> (C) agreement to the withholding of tranquilizers, anesthesia, analgesia, or euthanasia only when scientifically necessary and only for the necessary period of time; and
>
> (D) evaluation and approval of all animal surgical areas and qualifications of personnel involved with animal surgery.
>
> (ii) establish a recordkeeping system and standard operating procedure, which indicates and assures that the proper drugs are being used and that proper pre-surgical and post-surgical care, are being carried out on a daily basis; [1]

Forty-eight commenters stated that the areas provided in proposed paragraph (D) of § 2.40(e)(2)(i) should be the responsibility of the research facility, not the attending veterinarian. We agree that the areas listed in proposed paragraph (D) of subsection (e)(2)(i) (evaluation and approval of all animal surgical areas and qualifications of personnel involved with animal surgery) as well as those listed in proposed paragraphs (e)(2)(i)(A) through (C) are ultimately the responsibility of the research facility. We believe, however, they should be carried out with consultation and guidance from the attending veterinarian and in accordance with his or her instructions, because the attending veterinarian is best qualified to advise in these areas. Evaluation of animal surgical areas and the qualifications of personnel will be accomplished through the attending veterinarian in the revised rule, though they remain the ultimate responsibility of the facility.

We received 506 comments (481 from the research community and 25 from members of the general public) stating that proposed paragraph (e) of § 2.40 implied that the attending veterinarian would be required to be present during all actual research and that this is impractical and unnecessary. It is not our intent that the attending veterinarian must be present at all times during all actual research or during all actual research that might produce pain or distress in an animal. Rather our intent is that the attending veterinarian must be available for consultation and to provide guidance, and must have free access to all animal areas if he or she determines it is necessary to be present during the conduct of research procedures. During our consultations with representatives from HHS, they stated that many institutions interpreted proposed § 2.40(e) as requiring the attending veterinarian's presence. They suggested the following clarifying modification to paragraph (e)(2)(i): "Provide consultation and guidance to principal investigators and other laboratory personnel during [ACUP] planning and development, and if deemed necessary by the IACUC [Committee] during actual research, whenever any procedure is likely to produce pain or distress in an animal." We agree that the attending veterinarian should be present during actual research that is likely to produce pain or distress in animals if requested by the Committee. We also believe the attending veterinarian should be present if requested by the investigator, if complaints from personnel or humane groups are received, or to observe the research for compliance with the approved ACUP, the facility's written policy under § 2.30(e)(10), and the facility's program of adequate veterinary care. The revised rule is modified to clarify that the attending veterinarian's presence during actual research that is likely to produce pain or distress is required only under these circumstances.

[1] Paragraph (iii) is not repeated here since the requirement for the attending veterinarian to sign the annual report is removed from the revised rule.

One commenter objected to the requirement in proposed § 2.40(e)(2)(i) that the principal investigator consult with and receive guidance from the attending veterinarian during ACUP planning and development and during actual research whenever a procedure would be likely to produce pain or distress. Section 13(a)(3)(C)(i) of the Act specifically mandates this consultation in the planning of "any practice which could cause pain to animals." (7 U.S.C. 2143 (a)(3)(C)(i)). For this reason and for the reasons stated above in our discussion of required consultation and guidance, no change is made in the revised rule based upon this comment.

We received 40 comments stating that the requirement of proposed § 2.40(e)(2)(ii), that the attending veterinarian establish a recordkeeping system to assure proper drug usage and proper pre- and post-surgical care, be deleted. Twenty-nine commenters noted that procedures for proper drug use and pre- and post-surgical care would be provided in the ACUP, making a separate recordkeeping system unwarranted. We agree with the commenters insofar as requiring assurance of proper care is the institution's responsibility. We believe that the research facility should have some means of verifying the elements of proper veterinary care and that their written program of adequate veterinary care should provide for a recording system which indicates compliance with proper veterinary care procedures. We have revised paragraph (ii) in this rule to reflect that research facilities are required to have their attending veterinarian establish, as part of the facility's program of adequate veterinary care, procedures and a recording system in their program of adequate veterinary care which indicate and assure proper drug usage and proper pre- and post-procedural care.

Four commenters stated that only the institutional official responsible for animal care should be required to sign the annual report, Form VS 18–23. We agree for the reasons set forth under the heading, "Subpart B—Registration" and have removed paragraph (iii) from the revised rule.

No other changes are made to § 2.40 in the revised rule.

Subpart E—Identification of Animals, Time and method of identification

In proposed § 2.50, we proposed animal identification requirements intended to strengthen those of the existing regulations. We received 5 comments (2 from dealers and 3 from the general public) generally endorsing the stricter identification requirements and in favor of use of tags, tattoos, or both as the most reliable means of identification. One commenter urged that the type of marking provided in the regulations be by a humane method. Another commenter noted the need for requiring adequate recordkeeping as a means of verification of the animals' identity.

We have reconsidered the proposed requirements in light of the commenters' concern for stricter identification requirements in general. We believe that the requirements contained in proposed § 2.50 will result in more animals held by all classes of dealers and by research facilities being properly identified by tagging or by an approved tattoo. In this regard, we have reconsidered allowing class "A" dealers to identify live dogs or cats on the premises by "an accurate and distinctive description," a tattoo marking, or an official tag, and have determined that all animals on the premises should be identified by tattoo or official tag. We are eliminating the option to identify animals by description from proposed § 2.50(a)(3) since it could result in inaccuracies or improper substitution of animals. With this method of identification removed from the regulations, we believe that the requirements in paragraph (a)(3) can be combined with those of (a)(1). Accordingly, § 2.50(a)(1) is revised to require identification by tag or tattoo, of all live dogs and cats held on the premises, purchased, or otherwise acquired, sold, or otherwise disposed of or removed from the premises.

The commenter noting concern about humane methods of identification was most concerned that the method used not be unreasonably painful or distressful, such as ear tagging could be. The regulations are sufficiently clear in their requirement that tags must be attached "by means of a collar made of material generally considered acceptable to pet owners" and provides guidelines as to what would be considered acceptable and what would be unacceptable. Unacceptable materials are those such as wire, elastic, or sharp metal, that might cause discomfort or injury to the animals. Ear tagging is not an acceptable means of identification. We do not believe that additional regulations concerning the means of tagging are needed at this time.

Although we did not receive any comments addressing proposed § 2.50(b), we wish to clarify that it requires identification of all live dogs or cats under a Class "B" dealer's control, or on his premises, and not just those that are purchased or otherwise acquired. The word, "or," was inadvertently omitted from paragraph (b) in the proposal. To correct any misconception we are revising paragraph (b)(1) to read as follows:

"When live dogs or cats are held, purchased, or otherwise acquired, they shall be immediately identified—

We are making a conforming change in paragraph (c) for the same reason.

We did not receive any other comments concerning the remaining sections of proposed Subpart E, however we have determined that some revision is necessary.

We have clarified proposed § 2.50(e) by revising paragraph (e)(1) to include animals from any exempt source. Proposed paragraph (e)(2) is therefore removed from the revised rule because it is subsumed in paragraph (e)(1). We have revised proposed paragraph (e)(1) by redesignating its provisions as paragraphs (e)(1)(i), (ii), and (e)(2) in the revised rule to make it easier to follow. Paragraph (e)(1) of the proposed rule would provide that all live dogs or cats delivered for transportation, transported, purchased or otherwise acquired, sold, or disposed of by a research facility be identified at the time of delivery, purchase, sale, disposal, or acquisition by either: (1) An official tag or tattoo that was affixed to the animal at the time it was acquired by the research facility, or (2) a tag, tattoo, or collar applied to the dog or cat by the research facility which individually identifies the dog or cat by description or number. The latter alternative is redesignated as paragraph (e)(1)(ii) in the revised rule. We have determined that a tag, tattoo, or collar would identify the dog or cat by number only, and not by description, due to space and other practical limitations. We are removing identification by description from this provision in the revised rule.

Subpart F—Stolen Animals

Proposed § 2.60 would provide that "[a]ny person subject to the Act shall not buy, sell, exhibit, use for research, transport, or offer for transportation, any stolen animal." One of the findings of Congress on which the Act is premised is that "regulation of animals and activities as provided in [the] Act is necessary * * * in order (3) to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen." (7 U.S.C. 2131(b)). Section 2.60 was proposed in order to prevent the buying and selling of stolen animals and those obtained under questionable circumstances, since the requirements of marking for identification and

recordkeeping have proven insufficient to stop these practices.

We received 377 comments (352 from the research community and 25 from members of the general public) stating that proposed § 2.60 should either be deleted from the regulations entirely or that it should be limited to persons "knowingly or willfully" engaging in activities using stolen animals. Fourteen commenters (2 from the research community and 12 from members of the general public) stated that they are in favor of the proposed regulation.

As stated above, we have determined that this section is necessary and it remains in the rule, as revised. We have considered the comments stating that the regulations should prohibit only willful or knowing use of stolen animals and have determined that the resultant regulation would be ineffective and virtually unenforceable. We are concerned that persons seeking to use the animals as provided in the regulation would choose to remain ignorant of the circumstances under which the animal was obtained. We have also considered adding an exception for circumstances in which the person holding the animal has made reasonable, good faith efforts to determine whether the animal was stolen or its origin. We have determined that the proposed regulation would be most effective in preventing theft of animals if the various activities involving stolen animals listed in the regulation constitute a *per se* violation of the regulations. Only in this manner can we be certain that persons subject to the Act will use best efforts in endeavoring to avoid using stolen animals. We are hopeful that the incidence of stolen animals will subside if the market for them is eliminated. Section 2.60 remains in the revised rule as originally proposed.

Subpart G—Records

Dealers and exhibitors

We received 5 comments (1 from the research community, 1 from an exhibitor, and 3 from the general public) noting the need for stricter recordkeeping requirements in general. We believe that the additional recordkeeping requirements proposed in Subpart G will assist the Department by enhancing traceability of the animals, which is one of the prime objectives of the recordkeeping requirements, and will be a valuable tool in combatting the sale of animals obtained unlawfully.

We are clarifying § 2.75 in this revised rule to reflect that it applies to dealers other than operators of auction sales and brokers, and to exhibitors. This clarification is necessary because operators of auction sales and brokers are dealers under the Act (7 U.S.C. 2131(f)) and under the definition of "dealer" contained in Part 1—"Definition of Terms" (see companion docket no. 88–013, published elsewhere in this issue), because they negotiate the purchase or sale of animals, in commerce, for compensation or profit. Section 2.77 provides the recordkeeping requirements applicable to operators of auction sales and brokers to whom animals are consigned.

Proposed § 2.75 would impose recordkeeping requirements upon dealers and exhibitors that are substantially similar to those required under current § 2.75, except that dealers and exhibitors would also be required to maintain in their records the vehicle license number and state, and the driver's license number and state of anyone not licensed or registered under the Act from whom a dog or cat is acquired. This requirement was not included in proposed § 2.75(b) and we have determined that it is equally appropriate to include it for animals other than dogs and cats. This requirement was proposed to facilitate tracing the seller and the source of the animals, particularly when the source or origin of the animals is in question. Five commenters from the general public stated their approval of this requirement.

One member of the general public suggested that we require owner release statements which acknowledge ownership of the animals whenever they are acquired or sold, or possession is otherwise transferred. We are concerned that anyone who contrives to sell or transfer stolen animals would likely be willing to provide a fraudulent owner release statement. Secondly, a person subject to the Act might attempt to defend against a charge of violating § 2.60 by pleading good faith reliance on the owner release statement and could argue that it is not reasonable to require a person to go beyond obtaining the statement to satisfy themselves that the animals were not stolen. This would affect the Department's efforts to enforce § 2.60 of the regulations effectively under those circumstances or to prosecute persons charged for activities involving stolen animals. Because of these concerns with the commenter's suggestion, we are not requiring an owner release statement at this time. If we determine that it should be included in some form in the regulations, we will publish a notice of proposed rulemaking and solicit public comments on the proposal.

One exhibitor commented that APHIS, and not licensees, should maintain dealer records, such as the Record of Disposition of Dogs and Cats (VS Form 18–6). The Department is authorized under sections 10 and 12 of the Act to require that dealers and exhibitors maintain records with respect to the purchase, sale, transportation, identification, and previous ownership of animals (7 U.S.C. 2140, 2142). The Department is also authorized under sections 10 and 12 of the Act to inspect and copy those records (7 U.S.C. 2140, 2142). No change is made in the revised rule based upon this comment.

Section 2.75 remains as originally proposed.

Proposed 2.76 would similarly require research facilities to maintain in their records the vehicle license number and state, and the driver's license number and state of the person from whom a dog or cat was purchased or otherwise acquired if that person is not licensed or registered under the Act. Proposed § 2.76 would also require research facilities to maintain in their records the USDA license or registration number of that person if that person is licensed or registered under the Act. Current § 2.76 is more general in its requirement that research facilities maintain a license number if that person is licensed under the Act.

The requirement to maintain the vehicle license number and state, and the driver's license number and state of the person who owned or consigned the animal(s) for sale was omitted from proposed § 2.77(a). We have determined that it is equally appropriate to impose this requirement on dealers who are operators of auction sales and brokers, for the reasons stated above. Accordingly, § 2.77(a) is revised to include this requirement. We are also revising § 2.77(a) in this rule to include the date of birth or approximate age of the animal in the description required, because this requirement was inadvertently omitted from the proposed rule.

We received 303 comments (278 from members of the research community and 25 from members of the general public) stating that the requirement to maintain a record of the USDA license or registration number is not in the Act and that APHIS has failed to demonstrate how requiring it would benefit animal welfare. Section 10 of the Act requires research facilities to make and retain records with respect to the purchase, sale, transportation, identification, and previous ownership of live dogs and cats, as the Secretary may prescribe (7 U.S.C. 2140). Section 12 of the Act

authorizes the Secretary to promulgate recordkeeping requirements governing the purchase, handling, or sale of animals, in commerce, by research facilities (7 U.S.C. 2142). The requirement for maintaining a record of the USDA license or registration number of the person from whom live dogs or cats are obtained allows the Department to trace the origin of the animals and thereby locate dealers who may be suspected of selling unlawfully obtained animals. Without mechanisms which enable the Department to locate persons selling stolen animals, the Department would be unable to fulfill one of the stated purposes of the Act, "to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen." (7 U.S.C. 2131(b)(3)). Congress further authorized the Secretary "to promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of [the] Act." (7 U.S.C. 2151). The ability to trace persons selling animals is more important now than ever, because fewer pound animals are being conditioned for research purposes and the demand by the research facilities for experimental animals is increasing. There also appears to be increasing transfer of animals between research facilities, making it necessary to trace the sellers' identity through multiple previous owners. The requirement to obtain the license or registration number of all persons from whom a research facility obtains dogs or cats therefore remains as initially proposed, as it is necessary and reasonable under the circumstances.

Three members of the general public commented that the regulations should be revised to state that research facilities should buy animals from licensed sellers only. We believe that the Act fully covers this issue and that further regulation is not necessary. Section 7 of the Act provides:

> It shall be unlawful for any research facility to purchase any dog or cat from any person except an operator of an auction sale subject to section 12 of this Act or a person holding a valid license as a dealer or exhibitor issued by the Secretary pursuant to this Act unless such person is exempted from obtaining such license under section 3 of this Act. (7 U.S.C. 2137).

Proposed § 2.1 was intended to better identify persons exempt from the licensing requirements of the Act, as discussed in the supplementary information to Subpart A—Licensing, under the heading, "Requirements and application." We do not agree that additional provisions need be included in the regulations at this time No change is made in the revised rule as a result of this comment.

Health certification and identification

Proposed § 2.79 would continue the requirement of current § 2.79 that a health certificate, executed and issued by a licensed veterinarian, must accompany any dog, cat, or nonhuman primate delivered by a dealer, research facility, exhibitor, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government, to an intermediate handler or carrier for transportation in commerce. It further provides that VS Form 18–1 may be used for health certification by a licensed veterinarian. VS Form 18–1 is the "U.S. Interstate and International Certificate of Health Examination for Small Animals."

One commenter from the research community stated that federal institutions that are dealers are not required to sign Form 18–1. Nevertheless, the Act does require any "department, agency, or instrumentality of the United States having laboratory animal facilities," to provide health certificates (7 U.S.C. 2144). Section 14 of the Act requires that they comply with paragraphs (a), (f), (g), and (h) of section 13 (7 U.S.C. 2143), and section 13(f) provides the requirement for a health certificate to accompany dogs, cats, and "additional kinds or classes of animals designated by regulation of the Secretary." (7 U.S.C. 2144.)

We intended to impose these prohibitions on persons who transport animals in commerce themselves, rather than limiting the prohibitions to persons who deliver the animals to carriers or intermediate handlers, but inadvertently did not do so in the proposed rule. Imposing these prohibitions on persons who transport animals in commerce themselves is necessary because increasing numbers of dealers, research facilities, and other persons are transporting animals themselves, rather than using carriers and intermediate handlers to do so. The health and safety concerns underlying the minimum age requirement and health certification requirement apply equally to the animals in transport, regardless of the legal status of the person transporting the animal, and it is inconsistent with these concerns to place the prohibitions on carriers and intermediate handlers only.

Therefore, § 2.79 is revised in this rule by extending its prohibitions to any dealer, research facility, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government transporting any dog, cat, or nonhuman primate in commerce. This would apply to federal agencies as well. We are similarly extending the prohibition of § 2.130 to any person transporting dogs or cats in commerce.

We also note that in our proposal to amend Part 3—"Standards" (see companion docket no. 87–004, published elsewhere in this issue), we are proposing to make the transportation standards included in Subparts A–D applicable to any person subject to the Act who transports the regulated animals in commerce, rather than restricting the standards to carriers and intermediate handlers as in the current regulations.

Subpart H—Compliance with Standards and Holding Period

Compliance with standards

Proposed § 2.100(a) would require the following:

> Each dealer, exhibitor, operator of an auction sale and research facility shall comply in all respects with the regulations set forth in Part 2 and the standards set forth in Part 3 of this subchapter for the humane handling, care, treatment, housing, and transportation of animals: Provided, however: That exceptions to the standards in Part 3 may be made for research facilities only when such exceptions are specified in the research protocol; are explained in detail in a report filed with the Institutional Animal Care and Use Committee; and are approved by the Committee.

Seven commenters objected to the wording of proposed § 2.100(a). Four commenters from the research community objected to use of the term "research protocol" in the proposed regulation. Three of those commenters and 2 additional commenters from the research community stated that the statutory language should be used instead. A seventh commenter, also from the research community, stated that the phrase "are explained in detail in a report filed with the Institutional Animal Care and Use Committee; and are approved by the Committee" should be removed from the regulation.

We consider these comments to be unjustified. The proposed language is taken from the statute. Section 13(a)(3)(E) of the Act plainly states "that exception to such standards may be made only when specified by research protocol and that any such exception shall be detailed and explained in a report outlined under paragraph (7) and filed with the Institutional Animal Committee." (7 U.S.C. 2143(a)(3)(E).) The term "research protocol" is taken directly from the statute. However, as explained in Part 1—"Definition of

Terms," docket no. 88–013, published elsewhere in this issue of the **Federal Register**, we have replaced it with "animal care and use procedure" (ACUP) everywhere it appears in proposed Parts 1 and 2. This change is to satisfy concerns voiced by members of the research community and HHS that the Department would be interfering in research design. The requirement that exceptions to the standards be detailed and explained in a report to the Committee is also directly from the statute and remains in the revised rule. We are revising § 2.100 to also require that exceptions from the provisions of § 2.131, "Handling," may be made by research facilities when specified in the ACUP, explained in detail in a report filed with the Committee, and are approved by the Committee. This change is necessary because § 2.131 pertains to the humane handling of all animals covered by the Act and is derived from the standards in Part 3. We have included it in Part 2 because all persons subject to the Act must comply with it when handling all animals covered by the Act.

Proposed § 2.100(b) would apply to carriers and intermediate handlers, and would require that they comply with the regulations in Part 2 and the standards in Part 3 pertaining only to the humane transportation of animals in commerce. Proposed § 2.100(a) would apply to dealers, exhibitors, operators of auctions sales, and research facilities, and would require that they comply with the regulations in Parts 2 and 3 in their entirety. We have determined that because intermediate handlers hold animals for several days while awaiting transportation in commerce, they should be required to comply with all of the standards in Part 3 for the humane handling, care, treatment, and housing of animals during these holding periods, and not just those pertaining to transportation. We are therefore revising § 2.100(a) in the final rule to include intermediate handlers and we are removing them from § 2.100(b) in the revised rule.

Except for these three changes, § 2.100 remains as proposed.

Holding period

Proposed § 2.101(a) would require a 5-day holding period for dogs and cats by dealers and exhibitors following their acquisition of the animal. One dealer objected to the 5-day holding period. Section 5 of the Act provides as follows:

> No dealer or exhibitor shall sell or otherwise dispose of any dog or cat within a period of five business days after the acquisition of such animal or within such other period as may be specified by the Secretary * * * (7 U.S.C. 2135).

Five days is considered to be the appropriate holding period under most circumstances We consider that this is a reasonable period of time to allow persons to locate missing animals, and to enable a dealer or exhibitor to determine whether a dog or cat is fit for further transfer. Accordingly, the 5-day holding period remains in the revised rule. We are revising the rule, however, to ensure that animals are held 5 full days. We are concerned that if a dealer or exhibitor obtains an animal late in the day on a Monday, for example, that it could count that Monday as one business day and dispose of the animal early on Friday by counting Friday as one business day as well. This would not allow owners sufficient time to locate their missing animals. This problem would be compounded if the dealer or exhibitor is open for business over the weekend and counts Saturday and Sunday as business days. Using the time of acquisition in the example set forth above, an animal obtained late Thursday night might be disposed of first thing Monday morning, without allowing its owner a reasonable period of time to locate the missing animal. To prevent this occurrence, we are revising § 2.101(a) to provide that, except as otherwise provided in paragraph (a), any live dog or cat acquired by a dealer or exhibitor must be held for 5 full days, not including the day the animal was acquired. We are also providing that the 10-day holding period applicable to live dogs or cats acquired by a dealer or exhibitor from any private or contract pound or shelter excludes the day the animal was acquired.

We intended that all time periods provided in § 2.101 would exclude time in transit. This exclusion was inadvertently omitted from the initial requirement of paragraph (a) that "[a]ny live dog or cat acquired by a dealer [3] or exhibitor shall be held by him, under his supervision and control, for a period of not less than 5 business days after acquisition of such animal." Reference to excluding time in transit has been included in this revised rule, as well.

We proposed certain exceptions to the 5-day holding period in § 2.101(a). The second exception stated in the proposed regulation would allow dealers or exhibitors who obtained dogs or cats obtained from governmentally owned and operated pounds or shelters to hold the animals for only 24 hours, instead of the 5-day period otherwise required, if the animals completed a 5-day holding period at the governmentally owned and operated pound or shelter.

We received 5 comments from members of the general public objecting to the proposed exception for dealers and exhibitors who obtain dogs or cats from governmentally owned and operated pounds or shelters which would excuse them from the 5-day holding period. We agree with the commenters that this exception should be removed from the regulations. Based upon our review of the comments, we have determined that a 1-day holding period would not provide owners with a reasonable period of time to recover lost animals that have been placed in the pound or shelter, and that eliminating the 5-day holding period for dogs and cats obtained from governmentally owned and operated pounds or shelters would not be in the best interests of the animals or their owners and would not be in keeping with the intent of the Act. Therefore, we are retaining the 5-day holding period in the final rule for all dogs and cats obtained by a dealer or exhibitor, except as follows:

(1) In the revised rule we are requiring a 10-day holding period, not including the day of acquisition, for dogs and cats acquired or obtained by a dealer or exhibitor from a private or contract animal shelter or pound. A holding period for animals obtained from a private or contract shelter or pound was not included in the proposal because proposed § 2.132 would have prohibited class "B" dealers from obtaining random source dogs or cats from those sources. Accordingly, it was not necessary to provide a holding period. As explained below under the heading, "§ 2.132 Procurement of random source dogs and cats, dealers," the revised rule provides that class "B" dealers may obtain random source dogs and cats from private or contract pounds or shelters and must comply with the holding period required under §§ 2.101 and 2.132. We believe that a 10-day holding period for dogs and cats obtained from a private or contract pound is appropriate and reasonable because holding periods for these animals are determined by local laws and vary greatly. Holding periods may not even be required under some local laws. Moreover, animals held in private or contract pounds often are from several different towns or counties, depending upon the contract arrangement, and the 10-day period will allow owners additional time to locate lost or stolen animals;

(2) Dogs and cats that have completed a 5-day holding period with another dealer or exhibitor, or a 10-day holding period with another dealer or exhibitor if obtained from a private or contract shelter or pound, may be sold or

otherwise disposed of by subsequent dealers or exhibitors after a 24-hour holding period;

(3) Any dogs and cats suffering from disease, emaciation, or injury may be destroyed by euthanasia before completing the requisite holding period; and

(4) Any dogs and cats that are 120 days of age or less and that have been obtained from the person that bred and raised the animal may be disposed of by dealers or exhibitors after a 24-hour holding period.

The comments we received expressed concern that lost or stolen animals could be sold to research facilities before their owners are able to locate them. Proposed § 2.101 provides holding periods for dogs and cats that are applicable to dealers and exhibitors. One of the reasons for requiring holding periods is to allow owners of lost or stolen animals a reasonable time to locate their animals before they are sold or otherwise disposed of by the dealer or exhibitor.

We have determined that research facilities obtain dogs and cats from sources other than dealers and exhibitors which must comply with § 2.101, and exempt sources. Some of these dogs and cats may be lost or stolen animals. We believe that an effective way to protect owners of lost or stolen animals would be to impose a similar holding requirement on research facilities that obtain dogs and cats from those other sources.

Accordingly, we are requiring in this revised rule that research facilities that obtain dogs and cats from sources other than dealers, exhibitors, and exempt persons must hold the animals for 5 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit. Research facilities would still be subject to the identification of animals requirements in § 2.50. We believe that this measure is necessary to effectuate the purpose of the Act and that it is authorized under Section 21 of the Act (7 U.S.C. 2151).

We are revising paragraph (b) of § 2.101 to include reference to § 2.131, "Handling," for the reasons set forth above in this supplementary information, under the heading, "Holding period."

Holding facility

We are correcting a typographical error in proposed § 2.102(a)(3). That paragraph incorrectly references § 2.4. We have changed it in the revised rule to refer to § 2.1, as we intended.

Subpart I—Miscellaneous

Section 2.125 Information as to business

Proposed § 2.125 would require persons subject to the Act to provide to any Veterinary Services representative information concerning any business of theirs which may be requested in connection with enforcement of the Act and the Animal Welfare regulations. The proposal differs from the current regulation only in that carriers and intermediate handlers would also be required to furnish business information upon the request of a Veterinary Services representative. (Reference to "Veterinary Services representative" is changed to "APHIS official" in the revised rule.) The current regulation only applies to dealers, exhibitors, operators of auction sales, and research facilities.

We received 16 comments from the research community stating that the proposal would exceed our authority under the Act and that we have gone beyond the intent of the 1985 amendments to the Act. Another 4 commenters from the research community stated that proposed § 2.125 should be deleted for this reason. We believe these comments are unjustified, because the requirements contained in proposed § 2.125 have been in effect since 1967 with respect to dealers, exhibitors, and research facilities, and have not been subject to challenge. Nor have we encountered difficulty in obtaining compliance from the research community. Section 10 of the Act provides authority for requiring recordkeeping by dealers, exhibitors, and research facilities with respect to the "purchase, sale, transportation, identification, and previous ownership" of animals. Research facilities must make and retain required records with respect to live dogs and cats only. Authority to include carriers and intermediate handlers is specifically provided in Section 10 of the Act which further expressly requires that "[s]uch records shall be made available at all reasonable times for inspection and copying by the Secretary." (7 U.S C 2140.) Section 12 of the Act authorizes the Secretary to promulgate "recordkeeping requirements governing the purchase, handling, or sale of animals, in commerce, by dealers, research facilities, and exhibitors at auction sales and by the operators of such auction sales." (7 U.S.C. 2142.) Section 21 authorizes the Secretary to promulgate regulations in order to effectuate the purposes of the Act (7 U.S.C. 2151). The Department has determined that it is necessary to expand the scope of current § 2.125 to include carriers and intermediate handlers because of their increased involvement in handling animals in commerce. Expanding the scope of this regulation is also necessary to enhance enforcement efforts. We believe that ample authority is provided by the Act for requiring this information.

We received 302 comments (277 from the research community and 25 from members of the general public) objecting to proposed § 2.125 on the basis that the Act states that only those records required by the Act to be kept need to be made available to APHIS. Current and proposed § 2.125 would require the furnishing of any information "concerning the business of the [persons subject to the act] which may be requested by such representative [of APHIS] in connection with the enforcement of the provisions of the Act, the regulations and the standards in this subchapter." In order to carry out the Department's enforcement authority, Congress expressly authorized the Secretary to "promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of this Act." (7 U.S.C. 2151.) Authority to require that business information that is pertinent to enforcing the provisions of the Act and the Animal Welfare regulations be provided to the Department upon request is necessary in order to carry out the intent of Congress. This authority must apply equally to all information which may assist efforts to enforce the provisions of the Act and the regulations, but which is not specifically required to be kept by the Act, in order for the Department to be able to effectively enforce the regulations.

We received 48 comments (46 from the research community, 1 from an exhibitor, 1 from a member of the general public) suggesting we define "proprietary and business information" and clarify proposed § 2.125 to indicate that APHIS cannot use it to obtain proprietary information. We do not agree that these modifications are necessary. Current § 2.125 has been part of the Animal Welfare regulations since 1967. There have been no complaints that it has been wrongfully used to obtain proprietary information. The information required to be provided under the regulation is that which pertains to the conduct of business by persons subject to the Act. The information is necessary for the Department to effectively carry out its regulatory and enforcement authority under the Act.

For the above reasons no change is made to proposed § 2.125 in the revised rule.

One commenter from the research community stated that we should clarify the requirements for compliance by federal research facilities under proposed § 2.125. Federal research facilities are not required to be registered under the Act; however, they are directed to comply with "the standards and other requirements promulgated by the Secretary for a research facility under section 13 (a), (f), (g), and (h)." (7 U.S.C. 2144.) Except for the information required in the annual report of research facilities, they would not be required to furnish information to APHIS under § 2.125.

Section 2.126 Access and inspection of records and property

Proposed § 2.126 would require dealers, exhibitors, research facilities, intermediate handlers, and carriers to provide access to Department representatives for inspection of their premises, animals, and records, to copy records, and to take photographs to document conditions and/or areas of noncompliance. We received 193 comments from the research community stating that reference to access to records and to taking photographs should either be deleted from the section or that the proposal should be revised to limit access to records and photographing of the premises. We received 139 comments from the research community stating that the entire section should be deleted or revised within the limits of the Department's statutory authority under the Act. One commenter from the research community expressed concern that photographs could become available to the public through loss, theft, or FOIA requests. Statutory authority for Departmental access to conduct inspections of premises and records and to copy records is provided in Sections 10 and 16 of the Act (7 U.S.C. 2140, 2146). Section 10 of the Act requires persons subject to the Act to make and retain records as prescribed by the Secretary and provides that:

> [s]uch records shall be made available at all reasonable times for inspection and copying by the Secretary." (7 U.S.C. 2140).

Section 16 provides that:

> [t]he Secretary shall make such investigations or inspections as he deems necessary to determine whether [any person subject to the Act] has violated or is violating any provision of this Act or any regulation or standards issued thereunder, and for such purposes, the Secretary shall, at all reasonable times, have access to the places of business and the facilities, animals, and those records required to be kept pursuant to section 10 of any such [person]."

It further requires that these inspections be conducted at least once each year and that follow-up inspections be conducted until all deficiencies or deviations are corrected (7 U.S.C. 2146(a)).

The Department's authority to take photographs to document deficiencies has been upheld in an unpublished decision by a United States Court of Appeals following the Department's Judicial Officer's decision in *In re: Donald Stumbo, d.b.a. Stumbo Farms*, 43 Agric. Dec. 1079 (1984).

We believe that § 2.126 as proposed is within the Department's authority under the Act and that no revision is necessary.

Two dealers commented that Department representatives should make appointments before conducting inspections. We disagree with the commenters. The Act provides that the Secretary shall have access "at all reasonable times" (7 U.S.C. 2146(a)) and that persons subject to the Act must make their records available "at all reasonable times for inspection and copying by the Secretary." (7 U.S.C. 2140). We have found that the ability to conduct unannounced inspections enhances our enforcement efforts and is vital to encouraging actual and ongoing compliance with the Act. It is also necessary for determining whether inspection findings are reliable indicators of the actual conduct of business by the inspected entity. We are concerned that setting appointments would allow noncomplying persons to prepare for inspection, while operating at other times in noncompliance, because they feel secure they will not be inspected by the Department without warning. For this reason, no change is made in the revised rule based upon this comment.

We received 6 comments (4 dealers and 2 exhibitors) stating that the property surrounding an animal facility should either not be subject to inspection or that there should be a limit, such as 100 feet, on the surrounding area subject to inspection. Department representatives will continue to inspect surrounding land areas in order to detect problems with pests, odors, drainage, and trash or abandoned material, all of which can affect animal welfare. We agree that at some distance from a regulated person's permises, the condition of the area no longer has any bearing on the welfare of animals on the premises. However, the distance would vary in every situation, depending on the type of housing facility used, the area under the control of the regulated person, and other factors. Because these factors vary so widely and so unpredictably, it is not practical for us to specify a limit in the regulations.

We received 6 comments (5 from members of the research community and 1 dealer) stating that specific criteria should be established for the conduct of inspections by APHIS inspectors. As stated in proposed § 2.126, Department representatives will inspect facilities, property, records, and animals as considered necessary to enforce the provisions of the Act and the regulations and standards contained in Subchapter A—"Animal Welfare." The standards contained in Part 3—"Standards," provide specific site requirements which must be satisfied by persons subject to the Act holding animals. In a related document published elsewhere in this issue we are proposing standards applicable to dogs, cats, guinea pigs, hamsters, rabbits, and nonhuman primates. (*See* companion docket no. 87-004.) We believe that further specification of criteria is not necessary at this time. We encourage comments concerning the proposed standards, because they also contain criteria that will be used in conducting inspections.

One member of the general public commented that the regulations should include inspection of humane societies, animal shelters, pounds, and the like. These types of shelters are subject to regulation and inspection if they sell animals for a regulated purpose, such as to research facilities or to dealers.

Eleven commenters from the research community stated that federal facilities should be subject to inspection by the Department. We do not have authority under the Act to inspect facilities operated by federal agencies; however, they must comply with section 13 (a), (f), (g), and (h) of the Act, and must submit an annual report to APHIS each year. Accordingly, government owned and operated pounds are exempt from inspection by APHIS.

Section 2.128 Inspection for missing animals

Proposed § 2.128 would require dealers, exhibitors, research facilities, carriers, and intermediate handlers to allow access by "police or other officers of law enforcement agencies with general law enforcement authority (not those agencies whose duties are limited to enforcement of local animal regulations)" to enter the premises to inspect animals and records for the purpose of locating animals that are missing. Ten commenters from the research community stated that the section should be deleted from the regulations. One commenter stated that it violates the requirements of due

process of law and the Fourth Amendment protection against unreasonable searches and seizures. The commenter stated that searches for missing animals should be conducted under the existing procedures of local, state, and/or federal law enforcement agencies.

The Department is required by the Act to promulgate rules and regulations requiring persons subject to the Act to allow inspections to search for missing animals. Section 17 of the Act directs the Secretary to "promulgate rules and regulations requiring [persons subject to the Act] to permit inspection of their animals and records at reasonable hours upon request by legally constituted law enforcement agencies in search of lost animals." (7 U.S.C. 2147). Under the proposed rule, the searches must be conducted in accordance with the conditions and limitations provided in paragraphs (a) and (b) of § 2.128. Paragraph (a)(1) would require the law officer to furnish a written description of the missing animal, and the name and address of its owner before making the search. Accordingly, there must be a reasonable basis to believe that the animal is on the premises. We believe that § 2.128 does not violate any Constitutional rights. Cooperation to conduct these searches is required because the person holding a missing or stolen animal may not have any intent to do so and may not be aware that the animal has been stolen due to falsified shipping or purchase records. The regulations have required cooperation in searching for missing animals since 1967 without incident or challenge and remains in the revised rule.

Six commenters from the research community stated that the section should be clarified to include local animal regulations enforcement officers, humane association officers, and APHIS inspectors, and to extend the searches to animals undergoing experimentation or research procedures. We are unwilling to make these changes because the Act and the legislative history are clear that humane association and animal control officers are not authorized to conduct searches for missing animals. The officers conducting the searches must have general law enforcement authority, as required by the Act. Furthermore, both the Act and the legislative history underlying it are clear that Congress did not intend for the Department to interfere with the conduct of actual research (*See* H.R Report No. 1848 (August 11, 1966)). Nor did Congress intend for private persons or groups to use this provision as a means of interfering with research facilities by using it to gain entry.

Concern that APHIS is not authorized to search for missing animals is inappropriate. APHIS inspectors are authorized to inspect animals and animal records in the course of a regular inspection or an inspection to determine if there is a violation of the Act or any of the regulations, including § 2.60. The searches identified in § 2.128 are limited to those conducted by law enforcement agencies and so there is no need for mention of APHIS inspectors.

Accordingly, proposed § 2.128 remains as initially proposed.

Section 2.129 Confiscation and destruction of animals

We received 1 comment from the research community objecting to the reference to the International Union for the Conservation of Nature and Natural Resources (IUCN) in proposed § 2.129(c) as inappropriate because the U.S. Department of Interior, Fish and Wildlife Service (FWS) is statutorily authorized to identify and list threatened and endangered species. The commenter also suggested identifying nonhuman primates as an endangered species along with marine mammals. The commenter suggested that the Department should consult with the appropriate government agency having statutory authority regarding importation or use of an endangered species, once a confiscated animal has been identified as an endangered species. Proposed 2.129(c) would direct the Administrator to consult with certain agencies and the IUCN, when possible, before making any decision regarding destruction of a confiscated animal that is designated an endangered species.

Proposed § 2.129(c) concerns internal Agency procedure only and is not directed to any person subject to the Act and the regulations. Accordingly, we are removing it from the revised rule. Before making any decision regarding the destruction of a confiscated animal that is an endangered species, however, the Administrator will, when possible, consult with representatives of FWS, the National Marine Fisheries Service, Department of Commerce, or other appropriate government agencies, and the IUCN.

We did not receive any other comments concerning proposed § 2.129. However, we are revising this section to clarify that any animal confiscated under this section, not just certain ones, may be placed with other licensees or registrants which comply with the standards and regulations, and that the costs for this will be borne by the dealer, exhibitor, intermediate handler, carrier, or research facility from whom the animals were confiscated. In order to make this clear, we are breaking proposed § 2.129(b) into two portions, now designated as (b) and (c), and are making editorial changes to the proposed requirements. We are also removing the separate reference to operators of auction sales from paragraph (a) because they are dealers.

Section 2.130 Minimum age requirements

We did not receive any comments concerning proposed § 2.130. Proposed § 2.130 would prohibit any person from delivering a dog or cat to a carrier or intermediate handler for transportation in commerce unless the animal is at least 8 weeks of age and has been weaned. The only exception is for transportation in commerce to a registered research facility. We inadvertently failed to include a prohibition which would prevent any person subject to the Act from transporting a dog or cat in commerce by themselves, that is, without using a carrier or intermediate handler, unless the animal is at least 8 weeks of age and is weaned, except for transport in commerce to a research facility. We have included this prohibition in the revised rule.

Section 2.131 Handling

Sections 3.111 and 3.135 of Part 3—"Standards," Subparts E and F provide handling requirements for marine mammals and warmblooded animals other than dogs, cats, rabbits, hamsters, guinea pigs, and nonhuman primates respectively. Section 3.135 was included as part of Part 3, Subpart F, which was added when Congress amended the Act in 1970 to include all warmblooded animals used for research or exhibition purposes, or sold as pets. Section 3.111 was added in 1979 when standards covering marine mammals were added to Part 3. Subparts A through D do not contain comparable provisions. As stated in the supplementary information accompanying the proposed rule for Part 2, published March 31, 1987, 52 FR 10306, our experience has demonstrated the necessity for handling regulations to protect the welfare of all animals covered by the Act, and to enable the Department to better prosecute cases of inhumane handling and treatment. Accordingly, proposed § 2.131 would provide handling regulations applicable to all animals covered by the Act. In this revised rule, §§ 3.111 and 3.135 are removed from Part 3 and replaced with § 2.131.

Proposed § 2.131(a) would require that:

(a)(1) Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause unneccessary discomfort, trauma, overheating, excessive cooling, behavioral stress, or physical harm.

(2) Care shall be exercised to avoid harm to the handlers of such animals and to avoid unnecessary harm to the animals.

(3) Physical abuse or deprivation of food or water shall not be used to train, work, or otherwise handle animals.

Two commenters from the research community stated that proposed § 2.131 should be deleted from the final rule. One of the commenters objected that the requirement to protect animals from "unnecessary discomfort, trauma, overheating, excessive cooling, behavioral stress, or physical harm" is vague and that as proposed, a person subject to the Act would not understand their responsibilities under the regulations. Another 108 commenters from the research community objected to use of the term "behavioral stress" in proposed § 2.131(a)(1).

Proposed § 2.131 contains language, including that which the commenters objected to, that is substantially similar to the provisions of current §§ 3.111 and 3.135. Sections 3.111 and 3.135 have proven effective in enforcement efforts. They provide in part as follows:

(a) Handling of animals shall be done as expeditiously and carefully in a way so as not to cause unnecessary discomfort, behavioral stress, or physical harm to the animal. Care should be exercised also to avoid harm to the handler.

We have not been presented with any legal challenges to this language.

Our experience in enforcing these handling regulations has demonstrated the need for similar regulations for all animals covered by the Act. The Act requires that the Secretary promulgate minimum requirements to govern the humane handling of animals (7 U.S.C. 2143(a)(1)), Section 2.131 therefore remains in the revised rule. It should be noted that in accordance with §§ 2.30(g) and 2.35(b)(3) of the revised rule, exceptions to compliance with this regulation by a research facility in order to accomplish a research design must be explained in detail and justified by the ACUP, and must be approved by the Committee.

We are removing proposed paragraph (a)(2) from the revised rule because APHIS is charged with regulating the care of animals, not handlers, and because the requirement to exercise care to avoid unnecessary harm to the animals is contained in paragraph (a)(1). Accordingly, proposed paragraph (a)(3) is redesignated (a)(2) in this revision of Part 2.

We also received 99 comments (96 from members of the research community and 3 from exhibitors) objecting to proposed paragraph (a)(3) which concerns physical abuse and food and water deprivation, as unnecessarily restrictive and stating that its terms should either be defined and clarified or deleted. One commenter from the research community stated that the institutions should have responsibility for monitoring food or water deprivation. In the course of our consultation with representatives of HHS, they expressed concern that the proposed regulation was contrary to the Act's provision that the Act shall not be construed as "authorizing the Secretary to promulgate rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such facility; * * *" (7 U.S.C. 2143(a)(6)(A)). They stated that the withholding of food and other experimental methods should be addressed by the investigator, reviewed by peers, and reviewed by the Committee.

In response to the commenters, we again note that under §§ 2.30(g) and 2.35(b)(3), exceptions to compliance with this regulation by a research facility in order to accomplish a research design must be explained in detail and justified by the ACUP, and must be approved by the Committee. However, our experience has demonstrated the necessity to maintain this regulation prohibiting physical abuse or deprivation of food or water to train, work, or otherwise handle animals. These have been common methods of training animals in the past, as they are fast and simple and effective. But they can also be cruel and inhumane, and they are often unnecessary as other methods can accomplish the same ends in time. Paragraph (a)(3) therefore remains in the revised rule as proposed, except for one clarifying change. We have added the words "of animals" following "Physical abuse * * *."

Paragraph (b) of proposed § 2.131 would require as follows:

(b)(1) Animals shall be exhibited only for periods of time and under conditions consistent with their good health and well-being.

(2) A responsible and knowledgeable uniformed employee or attendant must be present at all times during periods of public contact.

(3) At a minimum, when dangerous animals such as lions, tigers, wolves, bears, or elephants are allowed to have contact with the public, the animals must be under the direct control and supervision of a knowledgeable and experienced animal handler.

(4) If public feeding of animals is allowed, the food must be provided by the animal facility and shall be appropriate to the type of animal and its nutritional needs and diet.

In addition to a comment from a member of the general public in support of proposed paragraph (b)(2), we received 2 comments (1 from an exhibitor and 1 from a member of the research community) stating that the term "uniformed" should be deleted from the paragraph.

Our intent in requiring a uniformed employee or attendant to be present at all times during periods of public contact was to ensure that the person responsible for the animal and knowledgeable about it was readily identifiable to members of the public. It is necessary that the viewing public be able to visually and readily determine who and where the attendant is at all times, both for the public's safety and for the safety of the animal. As uniforms are not necessarily available, and other means can be used to make an individual identifiable, we have replaced "uniformed" with the term "readily identifiable" in the revised rule in response to the comments.

Paragraph (c) of proposed § 2.131 would require as follows:

(c)(1) During public exhibition, any animal must be handled so there is minimal risk of harm to the animal and to the public, with sufficient distance and/or barriers between the animal and the general viewing public so as to assure safety to the animals and to the public.

(2) Performing animals shall be allowed a rest period between performances at least equal to the time for one performance.

(3) Young or immature animals shall not be exposed to rough or excessive public handling or exhibited for periods of time which would be detrimental to their health or well-being.

(4) Drugs, such as tranquilizers, shall not be used to facilitate, allow, or provide for public handling of the animals.

One member of the general public commented that the rest period that would be required under proposed paragraph (c)(2) should be extended to 3 times the performance time rather than a period of time equal to the performance time. Current §§ 3.111 and 3.135 require a rest period equal to the performance time. Experience with this requirement has demonstrated that it provides an adequate rest period. We are not aware of any negative behavior by performing animals or problems with the animals as a result of this length rest period. No change is made in proposed paragraph (c)(2) in the revised rule.

One member of the general public commented that dangerous animals should not be allowed contact with the public. The regulations in proposed paragraphs (b) and (c) of § 2.131 do not create a right of exhibitors to allow contact between wild or dangerous animals and the public. Proposed § 2.131(c) would require that in order to publicly exhibit an animal, an exhibitor must handle animals so that there is minimal risk of harm to the public. Proposed § 2.131(b) sets forth the conditions that apply to public exhibition of an animal if, and only if, handling an animal so that there is minimal risk of harm to the public would allow public exhibition. We are reversing the order of proposed paragraphs (b) and (c) in the revised rule in order to make clear that exhibitors do not have a right to allow contact between the public and dangerous animals.

Section 2.132 Procurement of random source dogs and cats, dealers

In order to carry out the intent of Congress and to "protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen" (7 U.S.C. 2131(b)(3)), we proposed to limit the sources from which class "B" dealers can acquire live random source dogs and cats. We proposed to limit those sources to State, county, or city owned and operated pounds or shelters. Under the proposed regulation, class "B" dealers would not be able to obtain random source dogs and cats from nongovernment pounds or shelters or from individuals who did not breed and raise the dogs and cats on their own premises. Nonrandom source dogs and cats could be obtained from persons who bred and raised the dogs and cats on their own premises.

One intended effect of the proposed regulation was to prevent the sale of random source dogs and cats to dealers at flea markets, auctions, and trade-day type sales. Our objective was to prevent the theft of animals for purposes of selling them to dealers who in turn would sell the stolen animals to research facilities.

Another intended effect of the proposed regulation was to eliminate the indiscriminate impoundment of "lost" animals by contract pound operators who are also licensed dealers. In the past several years, we have learned of increasing numbers of complaints and allegations that contract private animal pounds that are also licensed dealers under the Act have been overzealous in impounding dogs and cats. There are allegations that the impounded dogs and cats are not always stray or lost animals. In addition, the Agency has become aware of several instances where licensed dealers obtained stolen dogs and cats, or obtained dogs and cats under false pretenses or misrepresentation.

We proposed in § 2.132, to prohibit dealers from obtaining live random source dogs and cats from private or contract pounds or shelters, or from individuals who did not breed and raise the dogs and cats on their own premises. The proposed regulation would prevent operators of contract or private pounds or shelters from operating as class "B" dealers and selling their animals to research facilities. Our objective again was to prevent pound operators from obtaining dogs and cats from questionable sources, holding them for a short period, and then selling them to research facilities. We also intended to prevent pound operator-dealers from intermingling the animals and selling those dogs and cats that must be held by the pound operator for the requisite holding period pending identification and return to their owner, with those that have completed the requisite holding period and may be sold to research facilities or otherwise disposed of. The proposed regulation would also have the effect of preventing class "B" dealers from obtaining random source dogs and cats from other dealers for resale.

We received 2,865 comments from members of the general public supporting the proposed limitation of sources from which class "B" dealers can obtain random source dogs and cats. We also received 21 comments from members of the research community and 3 comments from dealers expressing support for proposed § 2.132.

We also received 167 comments from members of the research community objecting to the proposed regulation on the grounds that it exceeds our statutory authority, would limit the availability of animals for use by research facilities, and/or would increase the cost of animals to research facilities.

We believe that objections to the proposed regulation stating that it exceeds our statutory authority are incorrect. As expressed above and in the supplementary information to the proposal, preventing the theft of dogs and cats for the purpose of selling them to research facilities was one of the principal concerns prompting enactment of the Animal Welfare Act. To effectuate this purpose, the revised rule provides a number of measures, such as the records required by §§ 2.75 and 2.76 and the prohibition contained in § 2.60 against buying, selling, or using stolen animals, which were designed to prevent the sale of stolen animals and accordingly discourage the practice of stealing animals for sale to research facilities. Section 21 of the Act authorizes the Secretary to "promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of [the] Act." (7 U.S.C. 2151). The statutory authority for proposed § 2.132 is clear.

We have considered those comments which stated that preventing the sale of dogs and cats obtained from private or contract pounds or shelters would cut off a legitimate and valuable source of research animals and would drastically increase the cost of available animals. We understand that research facilities need a continuing source of dogs and cats for research. It was not our intent to reduce the available supply of dogs and cats for research purposes, but instead to exert better control over the source of dogs and cats for dealers.

To accommodate the need for a supply of research animals and to ensure that those animals are legally acquired by dealers for sale to research facilities, we are revising § 2.132 as follows: We are removing the prohibition against the purchase and sale of random source dogs and cats by dealers. We will allow dogs and cats from private or contract animal pounds to be obtained and sold by dealers and registrants, but with certain restrictions in order to better ascertain how, where, from whom, and when the dogs and cats were obtained by the pound, and when they were sold to the dealer. Any licensee or registrant who also operates a private or contract pound or shelter must maintain two physically separate and distinct animal facilities, one for the pound or shelter and one for the dealer or registered facility. The dealer or registrant must also maintain separate and accurate records at each facility. Dealers must comply with the 10-day holding period required in § 2.101, regardless of whether the dog or cat was obtained from a contract pound or shelter operated by the dealer or registrant, or from another contract pound or shelter.

Any licensee or registrant under the Act who also operates a private or contract pound or shelter must maintain records in accordance with §§ 2.75 and 2.76 for live nonrandom source dogs and cats. Because the information required by §§ 2.75 and 2.76 is not available for lost or stray animals, the following information is required to be maintained by the pound or shelter for lost or stray

dogs and cats: (1) An accurate description of the dog or cat; (2) how, where, from whom, and when the dog or cat was obtained; (3) how long the dog or cat was held by the pound or shelter before being transferred to the dealer operation; and (4) the date the dog or cat was transferred to the dealer operation. The information must be maintained in separate records, at both the pound or shelter and at the licensed or registered operation.

We believe that these restrictions and recordkeeping requirements will result in reducing the ease and temptation of transferring impounded animals to the dealer operation before any required holding period has been completed at the pound or shelter. They should also make it easier to trace the source of an animal in order to locate a missing dog or cat. We also believe that they will assist the Agency in our efforts to protect the owners of lost or stolen animals. These restrictions and recordkeeping requirements will provide us with adequate controls on the sale and movement of dogs and cats and will allow this resource to continue to be utilized as a source of research animals.

We are also revising § 2.132 to clarify that live nonrandom source dogs and cats may be obtained from hobby breeders, because the animals would have been bred and raised on the individual's premises.

We are including an express prohibition against any person subject to the Act obtaining random source dogs or cats by use of false pretenses, misrepresentation, or deception, as an additional safeguard against dealers using their other status as a pound or shelter to obtain dogs and cats and immediately transferring the animal to the dealer operation for sale to a research facility. This is also intended to prevent them from obtaining animals by claiming they will give it a "good home" and then selling it for research purposes.

We received 1 comment from a member of the research community stating that the regulations should allow dogs and cats held in government operated shelters to be available if they have been held for a 7-day period and there is public notice. This was not addressed in the regulations as the holding period at government pounds and the sale of animals held there is governed by local law. No change is made based upon this comment.

Statutory Authority

This rule is issued pursuant to the Animal Welfare Act (Act), as amended, 7 U.S.C. 2131–2157. Congress recently added significantly to the Secretary's responsibilities under the Act, particularly with regard to the use of animals by research facilities, in the Food Security Act of 1985, Pub. L. No. 99–198, approved December 23, 1985. The declared policy of the Act is to ensure that animals intended for use in research facilities, as pets, or for exhibition purposes, are provided humane care and treatment; to assure the humane treatment of animals during transportation; and to prevent the sale of stolen animals.

The Act requires that animal dealers and exhibitors obtain a license from the Secretary, and that research facilities, carriers, and intermediate handlers register with the Secretary. The Act directs the Secretary to issue specific regulations concerning, inter alia, recordkeeping, veterinary care, handling, transportation, identification of animals, and holding period requirements. In addition, the 1985 amendments require the Secretary to issue expanded regulations governing the use of animals in research facilities. Section 21 of the Act continues to authorize the Secretary to issue such regulations as he deems necessary to effectuate the purposes of the Act.

The recent amendments mandate that these regulations are to include standards for care, treatment, and practices in experimental procedures which will minimize pain and distress. The Secretary is to require that researchers consider alternatives to painful procedures and that, with regard to painful procedures, researchers must consult a veterinarian; use adequate tranquilizers, anesthetics, and analgesics; and provide for adequate pre- and post-surgical care. Moreover, exceptions to these standards may be made only when specified by research protocol and explained in a report mandated in the Act.

The Act also mandates that the Secretary issue regulations requiring research facilities to show and report that they are complying with the Act and that they are following professionally acceptable standards in the care and treatment of animals during research. The Act directs the Secretary to require each research facility to establish a committee to assess the facility's use and treatment of animals. The Act specifies the composition of the committee, including the requirement that each committee must be composed of at least three members and that each committee must have at least one member who is a veterinarian and at least one who represents the community interest in proper animal care. The Act mandates many of the committee's responsibilities, including that it inspect and report at least semi-annually on the condition and use of animals and report any violations of the standards. The Secretary is also to require each research facility to provide training for all personnel involved in animal care.

This rule contains regulations required by the 1985 amendments as well as modifications to existing regulations based on the Department's experience in administering the Act.

Executive Order 12291

On March 31, 1987, the Department published proposed rules to amend Part 1—"Definition of Terms" and Part 2—"Regulations," of the Animal Welfare regulations (52 FR 10292, 10298) in order to implement the 1985 amendments to the Animal Welfare Act, Pub. L. 99–198, the "Food Security Act." The proposed action was reviewed pursuant to Executive Order 12291 and it was determined that it did not constitute a "major rule." We solicited comments with regard to the proposed rules, and have made modifications to those rules as explained in the "Supplementary Information." At this time, we are also publishing a proposal to revise the standards contained in 9 CFR Part 3—"Standards," published elsewhere in this issue of the Federal Register.

In revising Parts 1 and 2, and in preparing the proposed rule for Part 3, we assessed the economic effects of the regulations in accordance with the requirements of Executive Order 12291. We considered alternative approaches to carrying out our statutory mandate, many of which we adopted. A regulatory impact analysis of revised Parts 1 and 2, and the proposal for Part 3 was prepared. Based on that analysis, which included consideration of both quantifiable and nonquantifiable effects of the rules, the Administrator has determined that Parts 1 and 2 would have an impact on the economy in excess of $100 million annually, and would constitute a "major rule."

The following requirements under Parts 1 and 2 represent some of the major costs to the regulated industries: (1) The establishment and responsibilities of the animal care and use committees; (2) aseptic surgical facilities and adequate pre- and post-procedural care; (3) increased responsibilities for attending veterinarians; (4) additional administrative responsibilities; (5) increases in license fees; and (6) identification for dogs and cats less than 16 weeks of age.

The economic impacts of these rules are discussed in more detail in a regulatory impact analysis, which is available for public inspection in Room

1141 of the South Building, U.S. Department of Agriculture between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays (address above). Main findings of this analysis are summarized below.

SUMMARY OF REGULATORY IMPACT ANALYSIS

Costs	Benefits
Direct	Direct
Regulated industry	Increased public satisfaction from improved animal welfare*
Capital expenditure:	
(All parts) $876 million	Improved research information*
(Parts 1-2) $142 million	Productivity gains for regulated industries*
Annual costs:	
(All parts) $207 million	
(Parts 1-2) $126 million	
APHIS program costs $2 million.	
Impact on Federal sites*	
Indirect	Indirect
Opportunity costs for users of biomedical research (goods and service), pet industry, and animal exhibits*.	Market effects for suppliers of animal husbandry products*
Increased Federal financial support for biomedical community*	Non-market effects*
Non-market effects*	

* Not quantified.

Compliance with more stringent federal regulations on the humane care and treatment of animals used for research, testing, teaching, exhibition, and business ventures would result in major direct and indirect effects imposed on the regulated industries and the general economy. An examination of the estimated cost impacts indicates that the amended regulations constitute a "major rule" based on annual effects in excess of $100 million on the economy and large cost increases on regulated industries for animal uses and maintenance, in particular to the biomedical research community. However, this study could not properly assess the relative significance of these cost increases on the regulated industry or the presence of adverse effects on competition innovation, and the ability of domestic enterprises to compete with foreign enterprises in international markets.

Regulated persons or establishments will be required to spend approximately $876 million in capital expenditures over the next two or three years. Of this amount approximately 16 percent is attributable to Parts 1 and 2. If Parts 1 and 2 were enforced separately, regulated research facilities will be required to spend approximately $142 million to renovate, equip, replace, or construct aseptic surgical facilities, and provide for adequate pre- and post-surgical care. Capital expenditures attributable to Part 3 include costs for renovation, equipment replacement, and new construction of animal housing facility space. Capital expenditures to improve animal housing facilities would result from the new minimum standards for general environmental conditions, space or primary enclosure size requirements, exercise of dogs, and enrichment of nonhuman primate enclosures.

In addition to capital expenditures, total annual operating expenditures estimated at $207 million will also be required. Approximately 60 percent of this total ($126 million) is accounted for by Parts 1 and 2, primarily the requirements for the establishment and operations of the institutional animal care and use committees, additional responsibilities for attending veterinarians, and record-keeping requirements. Annual expenditures attributable to Part 3 would result from the need for additional personnel (animal handlers) to exercise dogs, and the daily maintenance of animal housing facilities.

An important result of this regulatory analysis is that policy decisions must consider other direct and indirect effects associated with the promulgation and enforcement of federal rules. Increased federal legislation causes important economic benefits and costs which are unevenly distributed among registrants and licensees. Direct benefits accrue to society by knowing that animals may be better cared for and treated humanely. The value of these social benefits are subject to personal preferences and concerns. Improvements in the well-being of regulated animals may also provide gains in productivity to the industry. On the other hand, increased costs of compliance will be passed from the regulated industry to consumers who purchase their goods and services. For example, the field of biomedical research and education depends heavily on the use of animals to conduct tests and experiments. Increased costs for animal uses have broader economic and health implications for all of us. Study results do not suggest that these regulations would cause establishments to abandon the use of animals since current biomedical research outlays are in excess of $12.8 billion per year. Nonethelsss, there could be important effects associated with allocating additional funds or expenditures to comply with the amended animal welfare regulations.

Regulatory Flexibility Act

As part of the regulatory impact analysis performed by the Department we have analyzed the potential impact on small entities of Parts 1 and 2, as revised, and the proposal to amend Part 3 of the Animal Welfare regulations, as required by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Based upon our analysis, we have determined that Parts 1 and 2 of the regulations would affect all regulated small entities, primarily by increases in annual license fees and identification requirements for dogs and cats. However, these economic impacts would not be significant. It is anticipated that the largest impact on small entities would result from Part 3—"Standards", if it is implemented as proposed. Under these circumstances the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with state and local officials. (See 7 CFR 3015, Subpart V.)

Paperwork Reduction Act

In accordance with section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the information collection provisions that are included in this proposed rule will be submitted for approval to the Office of Management and Budget (OMB). Your written comments will be considered if you submit them to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. You should submit a duplicate copy of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 866, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

List of Subjects

9 CFR Part 2

Licensing, registration, identification of animals, records, Institutional Animal Care and Use Committees and Adequate Veterinary Care, Miscellaneous.

9 CFR Part 3

Animal welfare, Humane animal handling, Pets, Transportation.

Accordingly, we are proposing to amend 9 CFR Part 2 as follows:

1. Part 2 is revised to read as follows:

PART 2—REGULATIONS

Subpart A—Licensing

Sec.

Subpart B—Registration

Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities

Subpart D—Attending Veterinarian and Adequate Veterinary Care

Subpart E—Identification of Animals

Subpart F—Stolen Animals

Subpart G—Records

Subpart H—Compliance with Standards and Holding Period

Subpart I—Miscellaneous

Authority: 7 U.S.C. 2133, 2135, 2136, 2140–2144, 2146, 2147, 2151; 7 CFR 2.17, 2.51, and 371.2(d).

Subpart A—Licensing

§ 2.1 Requirements and application.

(a)(1) Any person operating or desiring to operate as a dealer, exhibitor, or operator of an auction sale, except persons who are exempted from the licensing requirements under paragraph (a)(3) of this section, must have a valid license. A person must be 18 years of age or older to obtain a license. A person seeking a license shall apply on a form which will be furnished by the Area Veterinarian in Charge in the State in which that person operates or intends to operate. The applicant shall provide the information requested on the application form, including a valid mailing address through which the licensee or applicant can be reached at all times, and a valid premises address where animals, animal facilities, equipment, and records may be inspected for compliance. The applicant shall file the completed application form with the Area Veterinarian in Charge.

(2) If an applicant for a license or license renewal operates in more than one State, he or she shall apply in the State in which he or she has his or her principal place of business. All premises, facilities, or sites where such person operates or keeps animals shall be indicated on the application form or on a separate sheet attached to it. The completed application form, along with the application fee indicated in paragraph (d) of this section, and the annual license fee indicated in table 1 or 2 of § 2.6 shall be filed with the Area Veterinarian in Charge.

(3) The following persons are exempt from the licensing requirements under section 2 or section 3 of the Act:

(i) Retail pet stores which sell nondangerous, pet-type animals, such as dogs, cats, birds, rabbits, hamsters, guinea pigs, gophers, domestic ferrets, chinchilla, rats, and mice, for pets, at retail only. *Provided that:* Anyone wholesaling any animals or selling any wild or exotic animals or other nonpet animals retail, or selling any animals for research or exhibition shall have a license;

(ii) Any person who sells or negotiates the sale or purchase of any animal except wild or exotic animals, dogs, or cats, and who derives no more than $500 gross income from the sale of such animals to a research facility, an exhibitor, a dealer, or a pet store during any calendar year and is not otherwise required to obtain a license;

(iii) Any person who maintains a total of three (3) or fewer breeding female dogs and/or cats and who sells the offspring of these dogs or cats, which were born and raised on their premises, for pets or exhibition, and is not otherwise required to obtain a license;

(iv) Any person who sells fewer than 25 dogs and/or cats per year which were born and raised on his or her premises, for research, teaching, or testing purposes or to any research facility and does not otherwise qualify for licensing. The sale of any dog or cat not born and raised on the premises for research purposes requires a license;

(v) Any person who arranges for transportation or transports animals solely for the purpose of breeding, exhibiting in purebred shows, boarding (not in association with commercial transportation), grooming, or medical treatment, and is not otherwise required to obtain a license;

(vi) Any person who buys, sells, transports, or negotiates the sale, purchase, or transportation of any animals used only for the purposes of food or fiber (including fur);

(vii) Any person who breeds and raises domestic pet animals for direct retail sales to others for his or her own use and who buys no animals for resale and who sells no animals to a research facility, an exhibitor, a dealer, or a pet store (e.g., a purebred dog or cat fancier) and does not otherwise qualify for licensing;

(viii) Any person who buys animals solely for his or her own use or enjoyment and does not sell or exhibit animals, or otherwise qualify for licensing.

(b) Any person who sells fewer than 25 dogs or cats per year for research or teaching purposes and who does not otherwise qualify for a license may obtain a voluntary license, provided the animals were born and raised on his or her premises. A voluntary licensee shall comply with the requirements for dealers set forth in this part and the Specifications for the Humane Handling, Care, Treatment, and Transportation of

Dogs and Cats set forth in Part 3 and shall agree in writing on a form furnished by APHIS to comply with all the requirements of the Act and this subchapter. Voluntary licenses will not be issued to any other persons. To obtain a voluntary license the applicant shall submit to the Area Veterinarian in Charge the application fee of $10 plus an annual license fee. The class of license issued and the fee for a voluntary license shall be that of a Class "A" licensee (breeder). Voluntary licenses will not be issued to any other persons or for any other class of license.

(c) No person shall have more than one license.

(d) A license will be issued to any applicant, except as provided in §§ 2.10 and 2.11, when the applicant:

(1) Has met the requirements of this section and of §§ 2.2 and 2.3; and

(2) Has paid the application fee of $10 and the annual license fee indicated in § 2.6 to the Area Veterinarian in Charge and the payment has cleared normal banking procedures.

(e)(1) On or before the expiration date of the license, a licensee who wishes a renewal shall submit to the Area Veterinarian in Charge a completed application form and the application fee of $10, plus the annual license fee indicated in § 2.6 by certified check, cashier's check, personal check, or money order. A voluntary licensee who wishes a renewal shall also submit the $10 application fee plus an annual license fee. An applicant whose check is returned by the bank will be charged a fee of $15 for each returned check. One returned check will be deemed nonpayment of fees and will result in denial of license. Payment of fees must then be made by certified check, cashier's check, or money order. An applicant will not be licensed until his or her payment has cleared normal banking procedures.

(2) The $10 application fee must also be paid if an applicant is applying for a changed class of license. The applicant may pay such fees by certified check, cashier's check, personal check, or money order. An applicant whose check is returned by a bank will be charged a fee of $15 for each returned check and will be required to pay all subsequent fees by certified check, money order, or cashier's check. A license will not be issued until payment has cleared normal banking procedures.

(f) The failure of any person to comply with any provision of the Act, or any of the provisions of the regulations or standards in this subchapter, shall constitute grounds for denial of a license, or for its suspension or revocation by the Secretary, as provided in the Animal Welfare Act.

§ 2.2 Acknowledgment of regulations and standards.

APHIS will supply a copy of the applicable regulations and standards to the applicant with each request for a license application or renewal. The applicant shall acknowledge receipt of the regulations and standards and agree to comply with them by signing the application form before a license will be issued or renewed

§ 2.3 Demonstration of compliance with regulations and standards.

(a) Each applicant must demonstrate that his or her premises and any animals, facilities, vehicles, equipment, or other premises used or intended for use in the business comply with the regulations and standards set forth in Parts 2 and 3 of this subchapter. Each applicant for an initial license or license renewal must make his or her animals, premises, facilities, vehicles, equipment, other premises, and records available for inspection during business hours and at other times mutually agreeable to the applicant and APHIS, to ascertain the applicant's compliance with the standards and regulations.

(b) In the case of an application for an initial license, the applicant must demonstrate compliance with the regulations and standards, as required in paragraph (a) of this section, before APHIS will issue a license. If the applicant's animals, premises, facilities, vehicles, equipment, other premises, or records do not meet the requirements of this subchapter, APHIS will advise the applicant of existing deficiencies and the corrective measures that must be completed to come into compliance with the regulations and standards. The applicant will have two more chances to demonstrate his or her compliance with the regulations and standards through re-inspection by APHIS. If the applicant fails the third inspection he or she will forfeit the application fee and cannot re-apply for a license for a period of 6 months following the third inspection. Issuance of the license will be denied until the applicant demonstrates upon inspection that the animals, premises, facilities, vehicles, equipment, other premises and records are in compliance with all regulations and standards in this Subchapter.

§ 2.4 Non-interference with APHIS officials.

A licensee or applicant for an initial license shall not interfere with, threaten, abuse (including verbal abuse), or harass any APHIS official in the course of carrying out his or her duties.

§ 2.5 Duration of license and termination of license.

(a) A license issued under this part shall be valid and effective unless:

(1) The license has been revoked or suspended pursuant to section 19 of the Act.

(2) The license is voluntarily terminated upon request of the licensee, in writing, to the Veterinarian in Charge.

(3) The license has expired or been terminated under this part.

(4) The applicant has failed to pay the application fee and the annual license fee as required in §§ 2.1 and 2.6. There will be no refund of fees if a license is terminated prior to its expiration date.

(b) Any person who is licensed must file an application for a license renewal and an annual report form (VS Form 18–3) as required by § 2.7, and pay the required fees, on or before the expiration date of the present license or the license shall expire and automatically terminate on its anniversary date. The licensee will be notified by certified mail at least 60 days prior to the expiration date of the license. Failure to comply with the annual reporting requirements, or to pay the required license fees prior to the expiration date of the license, shall result in automatic termination of such license on the anniversary date of the license.

(c) Licensees must accept delivery of registered mail or certified mail notice and provide the Area Veterinarian in charge notice of their address in conformity with the requirements in § 2.1.

(d) Any person who seeks the reinstatement of a license that has been automatically terminated must follow the procedure applicable to licensees set forth in § 2.1.

(e) Licenses are issued to persons for specific premises and do not transfer upon change of ownership, nor are they valid at a different location.

(f) A license which is invalid under this part shall be surrendered to the Area Veterinarian in charge. If the license cannot be found, the licensee shall provide a written statement so stating to the Area Veterinarian in charge.

§ 2.6 Annual license fees.

(a) In addition to the application fee of $10 required to be paid upon the application for a license, license renewal, or changed class of license under § 2.1, each licensee shall submit to the Area Veterinarian in Charge the

annual license fee prescribed in this section. Paragraph (b) of this section indicates the method used to calculate the appropriate fee. The amount of the fee is determined from Table 1 or 2 of this section.

(b)(1) Class "A" license. The annual license renewal fee for a Class "A" dealer shall be based on 50 percent of the total gross amount, expressed in dollars, derived from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale, by the dealer or applicant during his or her preceding business year (calendar or fiscal) in the case of a person who operated during such a year. If animals are leased, the lessor shall pay a fee based on 50 percent of any compensation received from the leased animals and the lessee shall pay a fee based upon the net compensation received from the leased animals, as indicated for dealers in Table 1 of this section.

(2) Class "B" license. The annual license renewal fee for a Class "B" dealer shall be established by calculating the total amount received from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale, during the preceding business year (calendar or fiscal) less the amount paid for the animals by the dealer or applicant. This net difference, exclusive of other costs, shall be the figure used to determine the license fee of a Class "B" dealer. If animals are leased, the lessor and lessee shall each pay a fee based on the net compensation received from the leased animals calculated from Table 1 of this section.

(3) The annual license renewal fee for a broker or operator of an auction sale shall be that of a class "B" dealer and shall be based on the total gross amount, expressed in dollars, derived from commissions or fees charged for the sale of animals, or for negotiating the sale of animals, by brokers or by the operator of an auction sale, to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, during the preceding business year (calendar or fiscal).

(4) In the case of a new applicant for a license as a dealer, broker or operator of an auction sale who did not operate during a preceding business year, the annual license fee will be based on the anticipated yearly dollar amount of business, as provided in paragraphs (b)(1), (2), and (3) of this section, derived from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale.

(5) The amount of the annual fee to be paid upon application for a class "C" license as an exhibitor under this section shall be based on the number of animals which the exhibitor owned, held, or exhibited at the time the application is signed and dated or during the previous year, whichever is greater, and will be the amount listed in Table 2. Animals which are leased shall be included in the number of animals being held by both the lessor and the lessee when calculating the annual fee. An exhibitor shall pay his or her annual license fee on or before the expiration date of the license and the fee shall be based on the number of animals which the exhibitor is holding or has held during the year (both owned and leased).

(c) The license fee shall be computed in accordance with the following tables:

TABLE 1.—DEALERS, BROKERS, AND OPERATORS OF AN AUCTION SALE—CLASS "A" AND "B" LICENSE

Over	But not over	Fee
$ 0	$ 500	$ 30
500	2,000	60
2,000	10,000	120
10,000	25,000	225
25,000	50,000	350
50,000	100,000	475
100,000		750

TABLE 2.—EXHIBITORS—CLASS "C" LICENSE

Number of Animals	Fee
1 to 5	$ 30
6 to 25	75
26 to 50	175
51 to 500	225
501 and up	300

(d) If a person meets the licensing requirements for more than one class of license, he shall be required to obtain a license and pay the fee for the type business which is predominant for his operation, as determined by the Secretary.

(e) In any situation in which a licensee shall have demonstrated in writing to the satisfaction of the Secretary that he or she has good reason to believe that the dollar amount of his or her business for the forthcoming business year will be less than the previous business year, then his or her estimated dollar amount of business shall be used for computing the license fee for the forthcoming business year: *Provided, however:* That if the dollar amount upon which the license fee is based for that year does in fact exceed the amount estimated, the difference in amount of the fee paid and that which was due under paragraphs (b) and (c) of this section based upon the actual dollar business upon which the license fee is based, shall be payable in addition to the required annual license fee for the next subsequent year, on the anniversary date of his or her license as prescribed in this section.

§ 2.7 Annual report by licensees.

(a) Each year, within 30 days prior to the expiration date of his or her license, a licensee shall file with the Area Veterinarian in Charge an application for license renewal and annual report upon a form which the Area Veterinarian in Charge will furnish to him or her upon request.

(b) A person licensed as a dealer shall set forth in his or her license renewal application and annual report the dollar amount of business, upon which the license fee is based, from the sale of animals, directly or through an auction sale, to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, by the licensee during the preceding business year (calendar or fiscal), and any other information as may be required thereon.

(c) A licensed dealer who operates as a broker or an operator of an auction sale shall set forth in his or her license renewal application and annual report the total gross amount, expressed in dollars, derived from commissions or fees charged for the sale of animals by the licensee to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, during the preceding business year (calendar or fiscal), and any other information as may be required thereon.

(d) A person licensed as an exhibitor shall set forth in his or her license renewal application and annual report the number of animals owned, held, or exhibited by him or her, including those which are leased, during the previous year or at the time he signs and dates the report, whichever is greater.

§ 2.8 Notification of change of name, address, control, or ownership of business.

A licensee shall promptly notify the Area Veterinarian in Charge by certified mail of any change in the name, address, management, or substantial control or ownership of his business or operation, or of any additional sites, within 10 days of any change.

§ 2.9 Officers, agents, and employees of licensees whose licenses have been suspended or revoked.

Any person who has been or is an officer, agent, or employee of a licensee whose license has been suspended or revoked and who was responsible for or participated in the violation upon which the order of suspension or revocation was based will not be licensed within the period during which the order of suspension or revocation is in effect.

§ 2.10 Licensees whose licenses have been suspended or revoked.

(a) Any person whose license has been suspended for any reason shall not be licensed in his or her own name or in any other manner within the period during which the order of suspension is in effect. No partnership, firm, corporation, or other legal entity in which any such person has a substantial interest, financial or otherwise, will be licensed during that period. Any person whose license has been suspended for any reason may apply to the Area Veterinarian in Charge, in writing, for reinstatement of his or her license.

(b) Any person whose license has been revoked shall not be licensed in his or her own name or in any other manner; nor will any partnership, firm, corporation, or other legal entity in which any such person has a substantial interest, financial or otherwise, be licensed.

(c) Any person whose license has been suspended or revoked shall not buy, sell, transport, exhibit, or deliver for transportation, any animal during the period of suspension or revocation.

§ 2.11 Denial of initial license application.

(a) A license will not be issued to any applicant who:

(1) Has not complied with the requirements of §§ 2.1, 2.2, 2.3, and 2.4 and has not paid the fees indicated in § 2.5;

(2) Is not in compliance with any of the regulations or standards in this subchapter;

(3) Has had a license revoked or whose license is suspended, as set forth in § 2.10;

(4) Has been fined, sentenced to jail, or pled nolo contendere (no contest) under State or local cruelty to animal laws within 1 year of application, except that if no penalty is imposed as a result of the plea of nolo contendere the applicant may reapply immediately; or

(5) Has made any false or fraudulent statements, or provided any false or fraudulent records to the Department.

(b) An applicant whose license application has been denied may request a hearing in accordance with the applicable rules of practice for the purpose of showing why the application for license should not be denied. The license denial shall remain in effect until the final legal decision has been rendered. Should the license denial be upheld, the applicant may again apply for a license 1 year from the date of the final order denying the application.

(c) No partnership, firm, corporation, or other legal entity in which a person whose license application has been denied has a substantial interest, financial or otherwise, will be licensed within 1 year of the license denial.

Subpart B—Registration

§ 2.25 Requirements and procedures.

(a) Each research facility other than a federal research facility, carrier, and intermediate handler, and each exhibitor not required to be licensed under section 3 of the Act and the regulations of this subchapter, shall register with the Secretary by completing and filing a properly executed form which will be furnished, upon request, by the Area Veterinarian in Charge. The registration form shall be filed with the Area Veterinarian in Charge for the State in which the registrant has his or her principal place of business, and shall be updated every 3 years by the completion and filing of a new registration form which will be provided by the Area Veterinarian in Charge. Where a school or department of a university or college uses or intends to use animals for research, tests, experiments, or teaching, the university or college rather than the school or department will be considered the research facility and will be required to register with the Secretary. An official who has the legal authority to bind the parent organization shall sign the registration form.

(b) In any situation in which a school or department of a university or college demonstrates to the Secretary that it is a separate legal entity and its operations and administration are independent of those of the university or college, the school or department will be registered rather than the university or college.

(c) A subsidiary of a business corporation, rather than the parent corporation, will be registered as a research facility or exhibitor unless the subsidiary is under such direct control of the parent corporation that the Secretary determines that it is necessary that the parent corporation be registered to effectuate the purposes of the Act.

§ 2.26 Acknowlegement of regulations and standards.

APHIS will supply a copy of the regulations and standards in this subchapter with each registration form. The registrant shall acknowledge receipt of and shall agree to comply with the regulations and standards by signing a form provided for this purpose by APHIS, and by filing it with the Area Veterinarian in Charge.

§ 2.27 Notification of change of operation.

(a) A registrant shall notify the Area Veterinarian in Charge by certified mail of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, exhibitor, carrier, or intermediate handler, within 10 days after making such change.

(b)(1) A registrant which has not used, handled, or transported animals for a period of at least 2 years may be placed in an inactive status by making a written request to the Area Veterinarian in Charge. A registrant shall file an annual report of its status (active or inactive). A registrant shall notify the Area Veterinarian in Charge in writing at least 10 days before using, handling, or transporting animals again after being in an inactive status

(2) A registrant which goes out of business or which ceases to function as a research facility, carrier, intermediate handler, or exhibitor, or which changes its method of operation so that it no longer uses, handles, or transports animals, and which does not plan to use, handle, or transport animals again at any time in the future, may have its registration cancelled by making a written request to the Area Veterinarian in charge. The former registrant is responsible for reregistering and demonstrating its compliance with the Act and regulations should it start using, handling, or transporting animals at any time after its registration is canceled.

Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities

§ 2.30 Additional requirements for research facilities.

(a) Each research facility using or holding animals for research, experimentation, testing, or teaching shall ensure:

(1) That animal pain and distress are minimized;

(2) That adequate veterinary care including the appropriate use of anesthetics, analgesics, tranquilizing drugs, or euthanasia, is provided at all times;

(3) That a written program of adequate veterinary care is established and maintained in accordance with § 2.40; and

(4) That animals are housed and cared for according to this subchapter and that any deviations are fully explained by the principal investigator and are approved by the Institutional Animal Care and Use Committee.

(b) Each research facility shall establish and maintain an Institutional Animal Care and Use Committee (Committee).

(c) Each research facility shall provide the Committee with the authority to enter all animal areas at any reasonable time and shall provide the attending veterinarian with the authority to enter all animal areas at any time, in order to carry out their responsibilities.

(d) Each research facility must require that the animal care and use procedure (ACUP) for any procedures and practices involving live warmblooded animals be approved by the Committee, prior to the start of research, testing, or teaching involving an animal; that the principal investigator consider alternatives to any procedure likely to produce pain or distress in an experimental animal; and that the principal investigator document such considerations in a written statement to the Committee as required by § 2.30(e).

(e) Each research facility that engages in any practice or procedure using an animal that might reasonably be expected to be a painful procedure must:

(1) Prior to the beginning of such practice or procedure, require that the principal investigator for each such practice or procedure provide written assurance to the Committee that:

(i) Alternative procedures have been considered and that no other procedures are suitable; and

(ii) The experiment does not unnecessarily duplicate previous experiments. The assurance must indicate what information sources were consulted, what other procedures were considered, and what techniques will be used to minimize pain and discomfort to the animals;

(2) Require that the principal investigator consult with the attending veterinarian during ACUP planning and development and during actual research, and ensure that the attending veterinarian is allowed access to all animal and research areas at any time during actual research:

(i) If deemed necessary by the Committee;

(ii) If requested by the investigator;

(iii) If in response to complaints regarding the research or procedures; or

(iv) If the attending veterinarian is observing the research for compliance with an approved ACUP, the facility's program of adequate veterinary care, or the facility's written policy established in accordance with paragraph (e)(10) of this section;

(3) Require that pain relieving drugs, anesthetics, analgesics, and tranquilizers are used to minimize pain unless they are withheld in accordance with the provisions of paragraph (4), and that they are administered in accordance with the directions and recommendations of the attending veterinarian and in accordance with the accepted or established use of the drugs;

(4) Require that pain relieving drugs, anesthetics, analgesics, and tranquilizers be reduced in amount or withheld only if scientifically necessary, and fully explained and justified in the ACUP and approved by the attending veterinarian and the Committee. The research facility must require that these drugs be reduced in amount or withheld only for as long as necessary as specified in the ACUP and approved by the Committee;

(5) Require that the attending veterinarian provide training of laboratory personnel in the proper use of pain relieving drugs, anesthetics, analgesics, and tranquilizers so as to minimize pain and distress;

(6) Require that all pre-procedural, procedural, and post-procedural care be provided by laboratory workers or surgical personnel in accordance with the instructions of the attending veterinarian and established veterinary medical and nursing procedures, and that this care and the qualifications of the personnel be evaluated and approved by the attending veterinarian;

(7) Require that all survival surgeries be conducted only in facilities intended for that purpose, that the facilities be operated and maintained under aseptic conditions, and that surgical rooms be evaluated and approved by the attending veterinarian;

(8) Require that any surgery be performed or directly supervised by trained, experienced personnel;

(9) Prohibit the use of paralytic drugs without anesthesia; and

(10) Establish a written policy to ensure compliance with paragraphs (e)(1) through (9) of this section.

(f)(1) Each research facility using or holding animals for research, testing or teaching shall establish and follow written procedures which assure that no animal is used in more than one major operative experiment from which it is allowed to recover except:

(i) When scientifically necessary and approved by the Committee;

(ii) When required by or related to other surgical procedures and approved by the Committee;

(iii) When required to reduce or conserve the number of marine mammals or endangered species of animals used and approved by the Committee;

(iv) When required to protect the health and well-being of the animal as determined by the attending veterinarian;

(v) When the procedure is a routine, elective veterinary surgical, or diagnostic procedure; or

(vi) In other special circumstances as determined by the Secretary on an individual basis. Written requests and supporting data should be sent to the Administrator, APHIS, USDA, 6505 Belcrest Road, Federal Building, Room 756, Hyattsville, MD 20782.

(2) Cost savings alone is not adequate reason for performing multiple survival surgical procedures.

(g) Exceptions. Exceptions to compliance with the standards and regulations set forth under Title 9 CFR, Chapter 1, Subchapter A—Animal Welfare, may be made by the research facility only when necessary in order to accomplish the research design, and when specified in the ACUP, explained in detail, and approved by the Committee. The principal investigator must file a report with the Committee prior to ACUP review explaining the areas of noncompliance in detail. A copy of the report must be kept on file by the facility and must be available for inspection by APHIS inspectors or officials of granting agencies. A copy of all written reports detailing and explaining exceptions to compliance with the standards and regulations must be attached to the facility's annual report.

(h) Exercise for dogs and psychological well-being of primates. The research facility shall establish, in consultation with the attending veterinarian, written procedures and systems for the exercise of dogs and for the psychological well-being of primates in accordance with the regulations and standards, and a record system documenting that such a procedure or system is being carried out.

(i) Training. (1) Each research facility shall provide for the training and continuing education of scientists, research technicians, animal technicians, and other personnel involved with animal use, care, and treatment at the facility.

(2) This training shall be reviewed by the Committee and the attending veterinarian, shall be appropriate to the

individuals and their responsibilities, and shall be made available annually or as appropriate to the individuals and their responsibilities.

(3) The research facility shall review the status of the training and qualifications of researchers to use animals at least once a year, and shall review the list of research personnel and shall designate those who require additional training. The review may be part of another review of personnel as long as the research facility has a written policy ensuring that all personnel are reviewed annually in these areas.

(4) This training shall be available for review by Department inspectors. Training shall include instruction in at least the following areas:

(i) Humane methods of animal maintenance and experimentation;

(ii) Research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress;

(iii) Utilization of the information service at the National Agricultural Library;

(iv) Methods whereby deficiencies in animal care and treatment should be reported;

(v) The basic needs of each species of animal;

(vi) Familiarization with the intent and requirements of the Animal Welfare Act;

(vii) How to handle and care properly for the various species of animals used by the facility;

(viii) Proper pre-procedural and post-procedural care of animals;

(ix) Proper use of anesthetics, analgesics, and tranquilizers in the species of animals used by the facility, including the common or accepted use of these drugs in those species for which the drug is not licensed;

(x) Acceptable aseptic surgical methods and procedures;

(xi) Other training, techniques, or procedures the research facility or the Secretary, may feel is necessary.

(j) *Procedures for personnel to report violations.* The research facility shall establish a reporting procedure whereby laboratory or research facility personnel or employees can report violations of any regulation or standard established under the Act including problems, deviations, or deficiencies with animal housing, care, or use. The Committee shall review and, if warranted, investigate any such reports, in addition to the twice yearly inspections, and shall prepare and file a report at the central location specified in § 2.30(m), indicating the nature of the problem or complaint, the Committee's findings, and any corrective actions taken. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standard under the Act.

(k) *Federal research facilities.* Each federal research facility shall establish an Institutional Animal Care and Use Committee which shall have the same composition, duties, and responsibilities required of nonfederal research facilities by this section and by § 2.35 with the following exceptions:

(1) The Committee shall report deficiencies to the head of the federal agency conducting the research rather than to APHIS;

(2) The head of the federal agency conducting the research shall be responsible for all corrective action to be taken at the facility and for the granting of all exceptions to inspection protocol.

(l) *Reviews.* Upon the request of the Administrator, the research facility shall make available for review all ACUPs involving animals and all assurance statements required by the U.S. Public Health Service (PHS) or any other funding Federal agency. APHIS inspectors will maintain the confidentiality of the information and will not remove the materials from the research facilities' premises unless there has been an alleged violation, or unless they are needed to investigate a possible violation or for other enforcement purposes.

(m) Reports. Any reports required by this part shall remain on file at a central location maintained by the research facility for at least 3 years and shall be available for inspection and review by APHIS officials and inspectors and any funding Federal agency. Upon notification from the Administrator, research facilities must retain specified records for more than 3 years pending completion of an investigation or proceeding under the Act, as required by § 2.81.

§ 2.31 Annual report of research facilities.

(a) The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, experiments, or for teaching. Each reporting facility shall submit an annual report to the Area Veterinarian in Charge for the State where the facility is located on or before December 1 of each calendar year. The report shall be signed and certified by the CEO or a responsible institutional official with authority to bind the facility, and shall cover the previous federal fiscal year.

(b) Such report shall:

(1) Assure that professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, during pre- and post-procedural care, and during actual research, teaching, testing, surgery, or experimentation were followed by the research facility;

(2) Assure that the principal investigator has considered alternatives to painful procedures;

(3) Assure that the facility is adhering to the standards and regulations under the Animal Welfare Act, and that it has required that exceptions to the standards and regulations be specified and explained by the ACUP and approved by the Committee. An explanation for any deviation from the standards and regulations shall be attached to the report;

(4) State the location of the facility or facilities where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes;

(5) State the common names and the numbers of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. Routine procedures (e.g., injections, tattooing, blood sampling) should be reported with this group;

(6) State the common names and the numbers of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used;

(7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. A detailed statement on the procedures producing pain or distress in these animals and explaining the reasons such drugs were not used shall be attached to the annual report;

(8) State the common names and the numbers of animals being bred, conditioned or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes; and

(9) Include a statement by the CEO or responsible institutional official with

authority to bind the facility that the Institutional Animal Care and Use Committee has authority to enter any animal or research area at any reasonable time, and that the attending veterinarian has authority to enter any animal or research area at any time, in order to carry out their responsibilities as set forth under §§ 2.35 and 2.40; and that the Committee has satisfactorily carried out its responsibilities; and that the facility complies with the Act, regulations, and standards.

(c) The CEO or responsible institutional official with authority to bind the facility shall certify on the annual report that the annual report was circulated to each member of the Committee and that each member of the Committee was given the opportunity to express concurrence or nonconcurrence with the report, and to attach a minority report to the annual report. The certification must indicate whether any member of the Committee indicated nonconcurrence. All minority reports provided to the CEO or responsible institutional official under this paragraph must be attached to the annual report. Each member's concurrence or nonconcurrence will be held confidential by the CEO and responsible institutional official.

§ 2.35 Institutional Animal Care and Use Committee.

(a) Membership.

(1) Each research facility shall establish and maintain an Institutional Animal Care and Use Committee (Committee);

(2) The members of each Committee shall be appointed by the Chief Executive Officer of the research facility;

(3) The Committee shall be composed of a Chairman and at least two additional members;

(4) Committee members shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility;

(5) Of the members of the Committee:

(i) At least one shall be a Doctor of Veterinary Medicine who is the attending veterinarian for the research facility. The Committee-related duties of the attending veterinarian may be delegated to a staff veterinarian in accordance with the written policy and procedures of the research facility;

(ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals;

(6) If the Committee consists of more than three members, not more than three members shall be from the same administrative unit of the facility;

(7) The research facility shall maintain an up-to-date list of Committee members and shall indicate for each member his or her name, degrees, position, and qualifications. The business address and telephone number of the Chairman must also be included on the list. A copy of the current list of Committee members shall be maintained by the attending veterinarian for the facility and shall be made available for inspection by APHIS officials.

(b) Duties and Responsibilities. (1) Inspections. (i) The Committee or a subcommittee composed of at least 2 Committee members shall inspect at least twice a year, 6 months apart, all animal study areas and animal facilities of the research facility and shall review as part of the inspection:

(A) All practices and procedures involving pain to animals; and

(B) The condition of all animals, in order to ensure compliance with the provisions of the Act to minimize pain and distress to the animals.

(ii) The Committee or subcommittee shall use Title 9, Chapter 1, Subchapter A—Animal Welfare, as a basis of its inspection of animal areas and facilities.

(iii) Exceptions to the requirement of inspection of animal study areas may be made by the Secretary if the animals are studied in their natural environment and the study area prohibits easy access. Requests for such exemption shall be addressed to the Administrator, APHIS, USDA, Room 756, 6505 Belcrest Road, Hyattsville, MD 20782, and shall clearly set forth the reasons why such inspections cannot be made.

(iv) The Committee may suspend or withdraw its approval of ACUPs for research, testing, or teaching involving pain to animals that it previously approved if it determines upon inspection that the practice or procedure is not being conducted in accordance with the previously approved ACUP or is not in accordance with the Animal Welfare Act, regulations, or standards. The Committee must direct the CEO or responsible institutional official to instruct the principal investigator to cease noncomplying activities immediately.

(v) No Committee member wishing to participate in an inspection conducted under this subpart may be excluded from participating in the inspection.

(vi) If the research facility maintains multiple animal sites, the Committee must complete its inspection of all animal study areas or animal facilities within 30 days of commencing the first inspection.

(2) Reports. (i) Committee inspection certification report. After each inspection performed by a subcommittee, the subcommittee must present its findings to a quorum of the Committee for approval and formal action. After each inspection is completed, or upon the approval of the presentation of findings if the inspection is performed by a subcommittee, the Committee must file an inspection certification report at a central location at the research facility established in accordance with § 2.30(m). The Committee must file its inspection certification report within 10 business days of completing its inspection of all animal study areas or animal facilities. The reports shall be available to APHIS officials and to officials of funding Federal agencies for inspection and copying. Inspection certification reports shall contain at least the following:

(A) The date the inspection was made;

(B) The signature of a majority of the Committee members and any minority views of the Committee;

(C) Reports of:

(*1*) Any violations of the regulations, standards, or assurances required by the Secretary, including any deficient conditions of animal care or treatment and any findings and recommendations of the Committee;

(*2*) Any deviations of research practices from originally approved ACUPs that adversely affect animal welfare;

(*3*) Any notification to the facility regarding such conditions, deviations, or deficiencies;

(*4*) Any corrections made by the facility; and

(*5*) Any other information pertinent to the activities of the Committee and the status or condition of the animal facilities; and

(D) An assurance statement by the Committee that its members have reviewed all painful procedures using animals and that the procedures:

(*1*) Are in accordance with the ACUPs approved by the Committee; or

(*2*) Are in accordance with any changes or special procedures approved by the Committee; or

(*3*) Are not in accordance with the approved ACUPs and that the Committee has notified the CEO or institutional official responsible for animal care to instruct the investigator(s) to cease such methods and procedures immediately and to comply with the ACUPs approved by

the Committee under paragraph (b)(3) of this section.

(ii) Deficiency notification reports.

(A) The Committee shall notify the CEO or institutional official responsible for animal care and the administrative unit representative, in writing, of any deficiencies in compliance with the Act, regulations, or standards found during an inspection, and of any noncompliance with an approved ACUP involving a painful procedure, within 1 business day of discovery of the deficiency. The Committee shall file a copy of the deficiency notification in the central location established at the research facility in accordance with § 2.30(m).

(B) The Committee shall provide the CEO or other institutional official responsible for animal care and the administrative unit representative with a copy of the report required under paragraph (b)(2)(i) of this section.

(C) If 30 days after notification of the deficiency any deficiency remains uncorrected, the Committee shall notify the Administrator and any funding Federal agency of the deficiency, in writing, within 5 business days of the expiration of the 30-day correction period. The Committee shall also provide a copy of its report and its notification of the deficiency to the Administrator and to any funding Federal agency.

(3) Reviews. (i) No research, testing, or teaching involving warm-blooded animals covered by the Act performed by a facility's personnel at any location shall commence prior to approval of the ACUP of the research, testing, or teaching by the Committee, nor shall it continue if the Committee withdraws or suspends its approval. An individual member of the Committee may be assigned to review an ACUP and to suggest needed modification of the ACUP to the principal investigator. The Committee member must present his or her recommendation for approval or disapproval to a quorum of the Committee for formal action. Prior to granting approval, the Committee shall ensure that the ACUP contains provisions for acceptable and proper animal care, treatment, practices, methods, and use of pain-relieving drugs. A quorum of the Committee must review a proposed ACUP upon the request of any member of the Committee.

(ii) The Committee shall approve an ACUP only when:

(A) Animal pain, distress, and functional or sensory impairment are minimized;

(B) All survival surgery is performed using aseptic procedures;

(C) Adequate veterinary care is planned for and provided;

(D) Proposed multiple use of animal(s) which undergo surgery is justified for the purpose of conserving an endangered species or marine mammals or as an essential related component of a particular project or ACUP; and

(E) Provision is made for the appropriate use of anesthetics, analgesics, tranquilizing drugs, or euthanasia when necessary, and that the use of these drugs is in accordance with established or accepted veterinary medical procedures and usage. The use of these drugs shall be in accordance with the instructions of the attending veterinarian.

Subpart D—Attending Veterinarian and Adequate Veterinary Care

§ 2.40 Attending veterinarian and veterinary care.

(a) Each research facility, dealer, or exhibitor shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section.

(b) Each research facility, dealer, or exhibitor shall establish and maintain programs of adequate veterinary care, including programs for disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, euthanasia, and the proper and appropriate use of anesthetics, analgesics, tranquilizers, and euthanasia when indicated, for all animals on the premises of the dealer, exhibitor, or research facility. These programs shall be under the supervision and control of the attending veterinarian.

(c) Written program of adequate veterinary care. (1) If a part-time or consulting attending veterinarian is utilized, the dealer, exhibitor, or research facility shall submit annually to the Area Veterinarian in Charge a written program of adequate veterinary care, prepared and signed by its attending veterinarian. The program shall include regularly scheduled visits by the attending veterinarian appropriate to the needs of the dealer, exhibitor, or research facility. The dealer, exhibitor, or research facility must keep a copy of the written program on file at the premises.

(2) If a full-time attending veterinarian is utilized, the dealer, exhibitor, or research facility shall have a written program of adequate veterinary care which will be reviewed by APHIS inspectors on the premises during inspections.

(3) The written program of adequate veterinary care shall include at least the following:

(i) The facility's name and address;

(ii) The veterinarian's name and address;

(iii) Provision for programs of disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, euthanasia, and the proper and appropriate use of anesthetics, analgesics, and tranquilizers;

(iv) How the programs are to be established and reviewed;

(v) The frequency of visits to be made to the premises by the veterinarian to assure adequate veterinary care and supervision of required programs;

(vi) The method or system of euthanasia to be utilized, by species, and who shall be authorized to perform it; and

(vii) The dated signature of the attending veterinarian and of a legally responsible official of the research facility, dealer, or exhibitor.

(d) Each animal shall be observed daily by the dealer, exhibitor, attending veterinarian, research facility, principal investigator, the animal caretaker in charge, or someone under the direct supervision of the attending veterinarian, principal investigator, or the animal caretaker in charge, who is required to report promptly his or her findings to trained personnel. Any necessary veterinary care shall be promptly provided. All research facilities, dealers, or exhibitors shall provide veterinary care to or humanely dispose of sick, diseased, injured, lame, or blind animals unless such action is inconsistent with the research purposes for which the animal was obtained and is being held: *Provided, however:* That this provision shall not affect compliance with any State or local law requiring the holding, for a specified period, of animals suspected of being diseased.

(e) Research facilities. (1) Each research facility shall require that the attending veterinarian be a member of the Committee and that he or she shall have the authority to enter all animal rooms, sites, facilities, animal use areas, and animal research areas at any time.

(2) In addition to the requirements set forth in paragraphs (a) through (d) of this section, the research facility shall require the attending veterinarian:

(i) To provide consultation and guidance to principal investigators and other laboratory personnel during ACUP planning and development, and during actual research, whenever any procedure is likely to produce pain or distress in an animal, if the attending veterinarian's presence and consultation is deemed necessary by the Committee,

is requested by the investigator, is in response to complaints regarding the research or procedures, or if the attending veterinarian is observing the research for compliance with the facility's written policy established in accordance with § 2.30(e)(10), an approved ACUP, or the written program of adequate veterinary care. Such consultation and guidance shall include at least the following:

(A) The proper use of tranquilizers, analgesics, anesthetics, and euthanasia according to the accepted, or common veterinary practice procedures;

(B) Provision for adequate pre- and post-procedural care by laboratory workers in accordance with current established veterinary medical and nursing procedures;

(C) Agreement to the withholding of tranquilizers, anesthesia, analgesia, or euthanasia only when scientifically necessary and only for the necessary period of time; and

(D) Evaluation and approval of all animal surgical areas and qualifications of personnel involved with animal surgery.

(ii) To establish, as part of the program of adequate veterinary care, procedures and a recording system which indicate and assure that the proper drugs are being used and that proper pre- and post-procedural care is being carried out on a daily basis.

Subpart E—Identification of Animals

§ 2.50 Time and method of identification.

(a) A class "A" dealer (breeder) shall identify all live dogs and cats on the premises as follows:

(1) All live dogs and cats held on the premises, purchased, or otherwise acquired, sold or otherwise disposed of, or removed from the premises for delivery to a research facility or exhibitor or to another dealer, or for sale, through an auction sale or to any person for use as a pet, shall be identified by an official tag of the type described in § 2.51 affixed to the animal's neck by means of a collar made of material generally considered acceptable to pet owners as a means of identifying their pet dogs or cats,[1] or shall be identified by a distinctive and legible tattoo marking acceptable to and approved by the Administrator.

(2) Live puppies or kittens, less than 16 weeks of age, shall be identified by:

(i) An official tag as described in § 2.51;

(ii) A distinctive and legible tattoo marking approved by the Administrator; or

(iii) A plastic-type collar acceptable to the Administrator which has legibly placed thereon the information required for an official tag pursuant to § 2.51.

(b) A class "B" dealer shall identify all live dogs and cats under his or her control or on his or her premises as follows:

(1) When live dogs or cats are held, purchased, or otherwise acquired, they shall be immediately identified:

(i) By affixing to the animal's neck an official tag as set forth in § 2.51 by means of a collar made of material generally acceptable to pet owners as a means of identifying their pet dogs or cats [1]; or

(ii) By a distinctive and legible tattoo marking approved by the Administrator.

(2) If any live dog or cat is already identified by an official tag or tattoo which has been applied by another dealer or exhibitor, the dealer or exhibitor who purchases or otherwise acquires the animal may continue identifying the dog or cat by the previous identification number, or may replace the previous tag with his own official tag or approved tattoo. In either case, the class B dealer or class C exhibitor shall correctly list both official tag numbers or tattoos in his or her records of purchase which shall be maintained in accordance with §§ 2.75 and 2.77. Any new official tag or tattoo number shall be used on all records of any subsequent sales by the dealer or exhibitor, of any dog or cat.

(3) Live puppies or kittens, less than 16 weeks of age, shall be identified by:

(i) An official tag as described in § 2.51;

(ii) A distinctive and legible tattoo marking approved by the Administrator; or

(iii) A plastic-type collar acceptable to the Administrator which has legibly placed thereon the information required for an official tag pursuant to § 2.51.

(4) When any dealer has made a reasonable effort to affix an official tag to a cat, as set forth in paragraphs (a) and (b) of this section, and has been unable to do so, or when the cat exhibits serious distress from the attachment of a collar and tag, the dealer shall attach the collar and tag to the door of the primary enclosure containing the cat and take measures adequate to maintain the identity of the cat in relation to the tag. Each primary enclosure shall contain no more than one weaned cat without an affixed collar and official tag, unless the cats are identified by a distinctive and legible tattoo or plastic-type collar approved by the Administrator.

(c) A class "C" exhibitor shall identify all live dogs and cats under his or her control or on his or her premises, whether held, purchased, or otherwise acquired:

(1) As set forth in (b)(1) or (b)(3) of this section, or

(2) By identifying each dog or cat with:

(i) An official USDA sequentially numbered tag that is kept on the door of the animal's cage or run;

(ii) A record book containing each animal's tag number, a written description of each animal, the data required by § 2.75(a), and a clear photograph of each animal; and

(iii) A duplicate tag that accompanies each dog or cat whenever it leaves the compound or premises.

(d) Unweaned puppies or kittens need not be individually identified as required by paragraphs (a) and (b) of this section while they are maintained as a litter with their dam in the same primary enclosure, provided the dam has been individually identified.

(e)(1) All live dogs or cats, including those from any exempt source, delivered for transportation, transported, purchased or otherwise acquired, sold, or disposed of by a research facility, shall be identified at the time of such delivery for transportation, purchase, sale, disposal, or acquisition in one of the following ways:

(i) By the official tag or tattoo which was affixed to the animal at the time it was acquired by the research facility, as required by this section; or

(ii) By a tag, tattoo, or collar, applied to the live dog or cat by the research facility and which individually identifies the dog or cat by number.

(2) Both official tag or tattoo numbers shall be correctly listed in the records of purchase, acquisition, disposal, or sale which shall be maintained in accordance with § 2.76.

(f)(1) All animals, except dogs and cats, delivered for transportation, transported, purchased, sold, or otherwise acquired or disposed of by any dealer or exhibitor shall be identified by the dealer or exhibitor at the time of delivery for transportation, purchase, sale, acquisition or disposal, as provided for in this paragraph and in records maintained as required in §§ 2.75 and 2.77.

[1] In general, well fitted collars made of leather or plastic will be acceptable under this provision. The use of certain types of chains presently used by some dealers may also be deemed acceptable. APHIS will determine the acceptability of a material proposed for usage as collars from the standpoint of humane considerations on an individual basis in consultation with the dealer or exhibitor involved. The use of materials such as wire, elastic, or sharp metal that might cause discomfort or injury to the dogs or cats is not acceptable.

(2) When one or more animals, other than dogs or cats, are confined in a container, the animal(s) shall be identified by:

(i) A label attached to the container which shall bear a description of the animals in the container, including:

(A) The number of animals;

(B) The species of the animals;

(C) Any distinctive physical features of the animals; and

(D) Any identifying marks, tattoos, or tags attached to the animals;

(ii) Marking the container with a painted or stenciled number which shall be recorded in the records of the dealer or exhibitor together with:

(A) A description of the animal(s);

(B) The species of the animal(s); and

(C) Any distinctive physical features of the animal(s); or

(iii) A tag or tattoo applied to each animal in the container by the dealer or exhibitor which individually identifies each animal by description or number.

(3) When any animal, other than a dog or cat, is not confined in a container, it shall be identified on a record, as required by § 2.75, which shall accompany the animal at the time it is delivered for transportation, transported, purchased, or sold, and shall be kept and maintained by the dealer or exhibitor as part of his or her records.

§ 2.51 Form of official tag.

(a) The official tag shall be made of a durable alloy such as brass, bronze, or steel, or of a durable plastic. Aluminum of a sufficient thickness to assure the tag is durable and legible may also be used. The tag shall be one of the following shapes:

(1) Circular in shape and not less than 1¼ inches in diameter, or

(2) Oblong and flat in shape, not less than 2 inches by ¾ inch and riveted to an acceptable collar.

(b) Each tag shall have the following information embossed or stamped on so that it is easily readable:

(1) The letters "USDA";

(2) Numbers identifying the State and dealer, exhibitor, or research facility (*e.g.*, 39–AB); and

(3) Numbers identifying the animal (*e.g.*, 82488).

(c) Official tags shall be serially numbered. No individual dealer, exhibitor, or research facility shall use any identification tag number more than once within a 5-year period.

§ 2.52 How to obtain tags.

Dealers, exhibitors, or research facilities may obtain, at their own expense, official tags from commercial tag manufacturers[2]. At the time the dealer, exhibitor, or research facility is issued a license or is registered, the Department will assign identification letters and numbers and inform them of the identification letters and numbers to be used on the official tags.

§ 2.53 Use of tags.

Official tags obtained by a dealer, exhibitor, or research facility, shall be applied to dogs or cats in the manner set forth in § 2.50 and in as close to consecutive numerical order as possible. No tag number shall be used to identify more than one animal. No number shall be repeated within a 5-year period.

§ 2.54 Lost tags.

Each research facility, dealer, or exhibitor shall be held accountable for all official tags acquired. In the event an official tag is lost from a dog or cat while in the possession of a research facility, dealer, or exhibitor, the research facility, dealer, or exhibitor shall make a diligent effort to locate and reapply the tag to the proper animal. If the lost tag is not located, the research facility, dealer, or exhibitor shall affix another official tag to the animal in the manner prescribed in § 2.50, and record the tag number on the official records.

§ 2.55 Removal and disposal of tags.

(a) When a dog or cat wearing or identified by an official tag arrives at a research facility, the facility may continue to use that tag to identify the dog or cat or the research facility may replace the tag as indicated in § 2.50(e). All tags removed by a research facility shall be retained and disposed of as indicated in this section.

(b) If a dealer, exhibitor, or research facility finds it necessary to euthanize a live dog or cat to which is affixed or which is identified by an official tag, or upon the death of a dog or cat from other causes, the dealer, exhibitor, or research facility shall remove and retain the tag for the required period, as set forth in paragraph (c) of this section.

(c) All official tags removed and retained by a dealer, exhibitor, or research facility shall be held until called for by an APHIS official or for a period of 1 year.

(d) When official tags are removed from animals for disposal, the tags must be disposed of so as to preclude their reuse for animal identification. No animal identification number shall be used within any 5-year period following its previous use.

[2] A list of the commercial manufacturers who produce these tags and are known to the Department may be obtained from the Area Veterinarian in Charge. Any manufacturer who desires to be included in the list should notify the Administrator.

Subpart F—Stolen Animals

§ 2.60 Prohibition on the purchase, sale, use, or transportation of stolen animals.

Any person subject to the Act shall not buy, sell, exhibit, use for research, transport, or offer for transportation, any stolen animal.

Subpart G—Records

§ 2.75 Records: Dealers and exhibitors.

(a)(1) Every dealer other than operators of auction sales and brokers to whom animals are consigned, and exhibitor shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each dog or cat purchased or otherwise acquired, owned, held, or otherwise in his or her possession or under his or her control, or which is transported, euthanized, sold, or otherwise disposed of by that dealer or exhibitor. The records shall include any offspring born of any animal while in his or her possession or under his or her control.

(i) The name and address of the person from whom a dog or cat was purchased or otherwise acquired whether or not the person is required to be licensed or registered under the Act;

(ii) The USDA license or registration number of the person if he or she is licensed or registered under the Act;

(iii) The vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under the Act;

(iv) The name and address of the person to whom a dog or cat was sold or given and that person's license or registration number if he or she is licensed or registered under the Act;

(v) The date a dog or cat was acquired or disposed of, including by euthanasia;

(vi) The official USDA tag number or tattoo assigned to a dog or cat under §§ 2.50 and 2.54;

(vii) A description of each dog or cat which shall include:

(A) The species and breed or type;

(B) The sex;

(C) The date of birth or approximate age; and

(D) The color and any distinctive markings;

(viii) The method of transportation including the name of the initial carrier or intermediate handler or, if a privately owned vehicle is used to transport a dog or cat, the name of the owner of the privately owned vehicle;

(ix) The date and method of disposition of a dog or cat, e.g., sale, death, euthanasia, or donation.

(2) Record of Dogs and Cats on Hand (VS Form 18–5) and Record of Disposition of Dogs and Cats (VS Form 18–6) are forms which may be used by dealers and exhibitors to make, keep, and maintain the information required by paragraph (a)(1) of this section.

(3) The USDA Interstate and International Certificate of Health Examination for Small Animals (VS Form 18–1) may be used by dealers and exhibitors to make, keep, and maintain the information required by paragraph (a)(1) of this section and § 2.79.

(4) One copy of the record containing the information required by paragraph (a)(1) of this section shall accompany each shipment of any dog or cat purchased or otherwise acquired by a dealer or exhibitor. One copy of the record containing the information required by paragraph (a)(1) of this section shall accompany each shipment of any dog or cat sold or otherwise disposed of by a dealer or exhibitor: *Provided, however:* That information which indicates the source and date of acquisition of a dog or cat need not appear on the copy of the record accompanying the shipment. One copy of the record containing the information required by (a)(1) of this section shall be retained by the dealer or exhibitor.

(b)(1) Every dealer other than operators of auction sales and brokers to whom animals are consigned, and exhibitor shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning animals other than dogs and cats, purchased or otherwise acquired, owned, held, leased, or otherwise in his or her possession or under his or her control, or which is transported, sold, euthanized, or otherwise disposed of by that dealer or exhibitor. The records shall include any offspring born of any animal while in his or her possession or under his or her control.

(i) The name and address of the person from whom the animals were purchased or otherwise acquired;

(ii) The USDA license or registration number of the person if he or she is licensed or registered under the Act;

(iii) The vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under the Act;

(iv) The name and address of the person to whom an animal was sold or given;

(v) The date of purchase, acquisition, sale, or disposal of the animal(s);

(vi) The species of the animal(s); and

(vii) The number of animals in the shipment.

(2) Record of Animals on Hand (other than dogs and cats) (VS Form 18.19) and Record of Acquisition, Disposition, or Transport of Animals (other than dogs and cats) (VS Form 18.20) are forms which may be used by dealers and exhibitors to keep and maintain the information required by paragraph (b)(1) hereof concerning animals other than dogs and cats except as provided in § 2.79.

(3) One copy of the record containing the information required by paragraph (b)(1) of this section shall accompany each shipment of any animal(s) other than a dog or cat purchased or otherwise acquired by a dealer or exhibitor. One copy of the record containing the information required by paragraph (b)(1) of this section shall accompany each shipment of any animal other than a dog or cat sold or otherwise disposed of by a dealer or exhibitor; *Provided, however:* That information which indicates the source and date of acquisition of any animal other than a dog or cat need not appear on the copy of the record accompanying the shipment. The dealer or exhibitor shall retain one copy of the record containing the information required by paragraph (b)(1) of this section.

§ 2.76 Records: Research facilities.

(a) Every research facility shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each live dog or cat purchased or otherwise acquired, owned, held, or otherwise in their possession or under their control, transported, euthanized, sold, or otherwise disposed of by such research facility. The records shall include any offspring born of any animal while in the research facility's possession or under its control.

(1) The name and address of the person from whom a dog or cat was purchased or otherwise acquired whether or not the person is required to be licensed or registered under the Act;

(2) The USDA license or registration number of the person if he or she is licensed or registered under the Act;

(3) The vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under the Act;

(4) The date of acquisition of each dog or cat;

(5) The official USDA tag number or tattoo assigned to each dog or cat under §§ 2.50 and 2.54;

(6) A description of each dog or cat which shall include:

(i) The species and breed or type of animal;

(ii) The sex;

(iii) The date of birth or approximate age; and

(iv) The color and any distinctive markings;

(7) Any identification number or mark assigned to each dog or cat by the research facility.

(b) In addition to the information required to be kept and maintained by every research facility concerning each live dog or cat under paragraph (a) of this section, every research facility transporting, selling, or otherwise disposing of any live dog or cat to another person, shall make and maintain records or forms which fully and correctly disclose the following information:

(1) The name and address of the receiver to whom a live dog or cat is transported, sold, or otherwise disposed of;

(2) The date of transportation, sale, euthanasia, or other disposition of the animal; and

(3) The method of transportation, including the name of the initial carrier or intermediate handler, or if a privately owned vehicle is used to transport the dog or cat, the name of the owner of the privately owned vehicle.

(c)(1) The USDA Interstate and International Certificate of Health Examination for Small Animals (VS Form 18–1) and Record of Dogs and Cats on Hand (VS Form 18–5) are forms which may be used by research facilities to keep and maintain the information required by paragraph (a) of this section.

(2) The USDA Interstate and International Certificate of Health Examination for Small Animals (VS Form 18–1), and Record of Disposition of Dogs and Cats (VS Form 18–6) are forms which may be used by research facilities to keep and maintain the information required by paragraph (b) of this section.

(d) One copy of the record containing the information required by paragraphs (a) and (b) of this section shall accompany each shipment of any live dog or cat sold or otherwise disposed of by a research facility: *Provided, however:* That information which indicates the source and date of acquisition of any dog or cat need not appear on the copy of the record accompanying the shipment. One copy of the record containing the information required by paragraphs (a) and (b) of this section shall be retained by the research facility.

§ 2.77 Records: Operators of auction sales and brokers.

(a) Every operator of an auction sale or broker shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each animal consigned for auction or sold, whether or not a fee or commission is charged:

(1) The name and address of the person who owned or consigned the animal(s) for sale;

(2) The name and address of the buyer or consignee who received the animal;

(3) The USDA license or registration number of the person(s) selling, consigning, buying, or receiving the animals if he or she is licensed or registered under the Act;

(4) The vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under the Act;

(5) The date of the consignment;

(6) The official USDA tag number or tattoo assigned to the animal under §§ 2.50 and 2.54;

(7) A description of the animal which shall include:

(i) The species and breed or type of animal;

(ii) The sex of the animal; and

(iii) The date of birth or approximate age; and

(iv) The color and any distinctive markings;

(8) The auction sales number or records number assigned to the animal.

(b) One copy of the record containing the information required by paragraph (a) of this section shall be given to the consignor of each animal, one copy of the record shall be given to the purchaser of each animal: *Provided, however:* That information which indicates the source and date of consignment of any animal need not appear on the copy of the record given the purchaser of any animal. One copy of the record containing the information required by paragraph (a) of this section shall be retained by the operator of such auction sale, or broker, for each animal sold by the auction sale or broker.

§ 2.78 Records: Carriers and intermediate handlers.

(a) In connection with all live animals accepted for shipment on a C.O.D. basis or other arrangement or practice under which the cost of an animal or the transportation of an animal is to be paid and collected upon delivery of the animal to the consignee, the accepting carrier or intermediate handler, if any, shall keep and maintain a copy of the guarantee in writing of the consignor of the shipment for the payment of transportation charged for any animal not claimed as provided in § 2.80, including, where necessary, both the return transportation charges and an amount sufficient to reimburse the carrier for out-of-pocket expenses incurred for the care, feeding, and storage of the animal. The carrier or intermediate handler at destination shall also keep and maintain a copy of the shipping document containing the time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee, as provided in § 2.80.

(b) In connection with all live dogs, cats, or nonhuman primates delivered for transportation, in commerce, to any carrier or intermediate handler, by any dealer, research facility, exhibitor, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government, the accepting carrier or intermediate handler shall keep and maintain a copy of the health certification completed as required by § 2.79, tendered with each live dog, cat, or nonhuman primate.

§ 2.79 Health certification and identification.

(a) No dealer, research facility, exhibitor, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government shall deliver to any intermediate handler or carrier for transportation, in commerce, or shall transport in commerce any dog, cat, or nonhuman primate unless the dog, cat, or nonhuman primate is accompanied by a health certificate executed and issued by a licensed veterinarian. The health certificate shall state that:

(1) The licensed veterinarian inspected the dog, cat, or nonhuman primate on a specified date which shall not be more than 10 days prior to the delivery of the dog, cat, or nonhuman primate for transportation; and

(2) When so inspected, the dog, cat, or nonhuman primate appeared to the licensed veterinarian to be free of any infectious disease or physical abnormality which would endanger the animal(s) or other animals or endanger public health.

(b) The Secretary may provide exceptions to the health certification requirement on an individual basis for animals shipped to a research facility for purposes of research, testing, or experimentation when the research facility requires animals not eligible for certification. Requests should be addressed to the Administrator, APHIS, USDA, Room 756, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

(c) No intermediate handler or carrier to whom any live dog, cat, or nonhuman primate is delivered for transportation by any dealer, research facility, exhibitor, broker, operator of an auction sale, or department, agency, or instrumentality of the United States or any State or local government shall receive a live dog, cat, or nonhuman primate for transportation, in commerce, unless and until it is accompanied by a health certificate issued by a licensed veterinarian in accordance with paragraph (a) of this section, or an exemption issued by the Secretary in accordance with paragraph (b) of this section.

(d) The U.S. Interstate and International Certificate of Health Examination for Small Animals (VS Form 18–1) may be used for health certification by a licensed veterinarian as required by this section.

§ 2.80 C.O.D. shipments.

(a) No carrier or intermediate handler shall accept any animal for transportation, in commerce, upon any C.O.D. or other basis where the cost of the animal or the cost for any transportation or any other incidental or out-of-pocket expense is to be paid and collected upon delivery of the animal to the consignee, unless the consignor guarantees in writing the payment of all transportation, including any return transportation, if the shipment is unclaimed or the consignee cannot be notified in accordance with paragraphs (b) and (c) of this section, including reimbursing the carrier or intermediate handler for all out-of-pocket expenses incurred for the care, feeding, and storage or housing of the animal.

(b)(1) Any carrier or intermediate handler receiving an animal at a destination on a C.O.D. or other basis where the cost of the animal or the cost for any transportation or other incidental or out-of-pocket expense is to be paid and collected upon delivery of the animal to the consignee shall attempt to notify the consignee at least once every 6 hours for a period of 24 hours after arrival of the animal at the animal holding area of the terminal cargo facility. The carrier or intermediate handler shall record the time, date, and method of each attempted notification and the final notification to the consignee, and the name of the person notifying the consignee, on the shipping document and on the copy of the shipping document accompanying the C.O.D. shipment. If the consignee cannot be

notified of the C.O.D. shipment within 24 hours after its arrival, the carrier or intermediate handler shall return the animal to the consignor, or to whomever the consignor has designated, on the next practical available transportation, in accordance with the written agreement required in paragraph (a) of this section and shall notify the consignor. Any carrier or intermediate handler which has notified a consignee of the arrival of a C.O.D. or other shipment of an animal, where the cost of the animal, or the cost for any transportation, or other incidental or out-of-pocket expense is to be paid and collected upon delivery of the animal to the consignee, which is not claimed by the consignee within 48 hours from the time of notification, shall return the animal to the consignor, or to whomever the consignor has designated, on the next practical available transportation, in accordance with the written agreement required in paragraph (a) of this section and shall notify the consignor.

(c) It is the responsibility of any carrier or intermediate handler to provide care, feed, and hold properly any animal accepted for transportation, in commerce, under a C.O.D. or other arrangement where the cost of the animal or the cost of any transportation or other incidental or out-of-pocket expense is to be paid and collected upon delivery of the animal until the consignee accepts shipment at destination or until returned to the consignor or his or her designee should the consignee fail to accept delivery of the animal or if the consignee could not be notified as prescribed in paragraph (b) of this section.

(d) Nothing in this section shall be construed as prohibiting any carrier or intermediate handler from requiring any guarantee in addition to that required in paragraph (a) of this section for the payment of the cost of any transportation or out-of-pocket or other incidental expenses incurred in the transportation of any animal.

§ 2.81 Records, disposition.

(a) No dealer, exhibitor, broker, operator of an auction sale, research facility, carrier, or intermediate handler shall, for a period of 1 year, destroy or dispose of, without the consent in writing of the Administrator, any books, records, documents, or other papers required to be kept and maintained under this part.

(b) Unless otherwise specified, the records required to be kept and maintained under this part shall be held for 1 year after an animal is euthanized or disposed of and for any period in excess of one year as necessary to comply with any applicable Federal, State, or local law. Whenever the Administrator notifies a dealer, exhibitor, broker, operator of an auction sale, research facility, carrier, or intermediate handler in writing that specified records shall be retained pending completion of an investigation or proceeding under the Act, the dealer, exhibitor, broker, operator of an auction sale, research facility, carrier, or intermediate handler shall hold those records until their disposition is authorized by the Administrator.

Subpart H—Compliance With Standards and Holding Period

§ 2.100 Compliance with standards.

(a) Each dealer, exhibitor, operator of an auction sale, intermediate handler, and research facility shall comply in all respects with the regulations set forth in Part 2 and the standards set forth in Part 3 of this subchapter for the humane handling, care, treatment, housing, and transportation of animals: *Provided, however:* That exceptions to the standards in Part 3 and the provisions of § 2.131 may be made for research facilities only when such exceptions are specified in the animal care and use procedure (ACUP), are explained in detail in a report filed with the Committee, and are approved by the Committee.

(b) Each carrier shall comply in all respects with the regulations in Part 2 and the standards in Part 3 setting forth the conditions and requirements for the humane transportation of animals in commerce and their handling, care, and treatment in connection therewith.

§ 2.101 Holding period.

(a) Any live dog or cat acquired by a dealer [3] or exhibitor shall be held by him or her, under his or her supervision and control, for a period of not less than 5 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit: *Provided, however:*

(1) That any live dog or cat acquired by a dealer or exhibitor from any private or contract animal pound or shelter shall be held by that dealer or exhibitor under his or her supervision and control for a period of not less than 10 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit;

(2) Live dogs or cats which have completed a 5-day holding period with another dealer or exhibitor, or a 10-day holding period with another dealer or exhibitor if obtained from a private or contract shelter or pound, may be sold or otherwise disposed of by subsequent dealers or exhibitors after a minimum holding period of 24 hours by each subsequent dealer or exhibitor, excluding time in transit;

(3) Any dog or cat suffering from disease, emaciation, or injury may be destroyed by euthanasia prior to the completion of the holding period required by this section; and

(4) Any live dog or cat, 120 days of age or less, that was obtained from the person that bred and raised such dog or cat, may be exempted from the 5-day holding requirement and may be disposed of by dealers or exhibitors after a minimum holding period of 24 hours, excluding time in transit. Each subsequent dealer or exhibitor must also hold each such dog or cat for a 24-hour period excluding time in transit.

(b) During the period in which any dog or cat is being held as required by this section, the dog or cat shall be unloaded from any means of conveyance in which it was received, for feed, water, and rest, and shall be handled, cared for, and treated in accordance with the standards set forth in Part 3, Subpart A, of this subchapter and § 2.131 of this part.

(c) Research facilities that obtain dogs and cats from sources other than dealers, exhibitors, and exempt persons shall hold the animals for 5 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit, before they may be used by the facility. Research facilities shall comply with the identification of animals requirements set forth in § 2.50 during this period.

§ 2.102 Holding facility.

(a) If any dealer or exhibitor obtains the prior approval of the Area Veterinarian in Charge, he may arrange to have another person hold animals for the required period provided for in paragraph (a) of § 2.101: *Provided that:*

(1) The other person agrees in writing to comply with the regulations in Part 2 and the standards in Part 3 of this subchapter and to allow inspection of his premises by an APHIS official during business hours; and

(2) The animals remain under the total control and responsibility of the dealer or exhibitor.

(3) Approval will not be given for a dealer or exhibitor holding a license as set forth in § 2.1 to have animals held for purposes of this section by another licensed dealer or exhibitor. Veterinary

[3] An operator of an auction sale is not considered to have acquired a dog or cat which is sold through the auction sale.

Services Form 18.9 shall be used for approval.

(b) If any research facility or intermediate handler obtains prior approval of the Area Veterinarian in Charge, it may arrange to have another person hold animals: *Provided that:*

(1) The other person agrees in writing to comply with the regulations in Part 2 and the standards in Part 3 of this subchapter and to allow inspection of the premises by an APHIS official during business hours;

(2) The animals remain under the total control and responsibility of the research facility or intermediate handler; and

(3) In the case of a research facility, a legally responsible official of the research facility agrees in writing that the other person or premises is a recognized animal site under its research facility registration. Veterinary Services Form 18.9 shall be used for approval.

Subpart I—Miscellaneous

§ 2.125 Information as to business; furnishing of same by dealers, exhibitors, operators of auction sales, research facilities, intermediate handlers, and carriers.

Each dealer, exhibitor, research facility, intermediate handler, and carrier shall furnish to any APHIS official any information concerning the business of the dealer, exhibitor, operator of an auction sale, research facility, intermediate handler or carrier which the APHIS official may request in connection with the enforcement of the provisions of the Act, the regulations and the standards in this subchapter. The information shall be furnished within a reasonable time and as may be specified in the request for information.

§ 2.126 Access and inspection of records and property.

(a) Each dealer, exhibitor, research facility, intermediate handler, or carrier, shall, during business hours, allow APHIS officials:

(1) To enter its place of business;

(2) To examine records required to be kept by the Act and the regulations in this part;

(3) To make copies of the records;

(4) To inspect the facilities, property and animals, as the APHIS officials consider necessary to enforce the provisions of the Act, the regulations and the standards in this subchapter; and

(5) To take photographs to document conditions and/or areas of noncompliance in the facility.

(b) The use of a room, table, or other facilities necessary for the proper examination of the records and inspection of the property or animals shall be extended to APHIS officials by the dealer, exhibitor, research facility, intermediate handler or carrier, or his agents and employees.

§ 2.127 Publication of names of persons subject to the provisions of this part.

APHIS will publish lists of persons licensed or registered in accordance with the provisions of this part in the Federal Register. The lists may be obtained upon request from the Area Veterinarian in Charge.

§ 2.128 Inspection for missing animals.

(a) Each dealer, exhibitor, research facility, intermediate handler and carrier shall, upon request, during business hours, allow, under the following conditions, police or officers of other law enforcement agencies with general law enforcement authority (not those agencies whose duties are limited to enforcement of local animal regulations) to enter his or her place of business to inspect animals and records for the purpose of seeking animals that are missing:

(1) The police or other law officer shall furnish to the dealer, exhibitor, research facility, intermediate handler or carrier a written description of the missing animal and the name and address of its owner before making a search.

(2) The police or other law officer shall abide by all security measures required by the dealer, exhibitor, research facility, intermediate handler or carrier to prevent the spread of disease, including the use of sterile clothing, footwear, and masks where required, or to prevent the escape of an animal.

(b) An inspection for missing animals by law enforcement officers shall not extend to animals that are undergoing actual research or experimentation by a research facility as determined by the research facility.

§ 2.129 Confiscation and destruction of animals.

(a) If an animal being held by a dealer, exhibitor, intermediate handler, carrier, or by a research facility when it is no longer required by the research facility to carry out the research, test, or experiment for which it has been utilized, is found by an APHIS official to be suffering as a result of the failure of the dealer, exhibitor, intermediate handler, carrier, or research facility to comply with any provision of the regulations or the standards set forth in this subchapter, the APHIS official shall make a reasonable effort to notify the dealer, exhibitor, intermediate handler, carrier, or research facility of the condition of the animal(s) and request that the condition be corrected and that adequate care be given when necessary to alleviate the animal's suffering or distress, or that the animal(s) be destroyed by euthanasia. In the event that the dealer, exhibitor, intermediate handler, carrier, or research facility refuses to comply with this request, the APHIS official may confiscate the animal(s) for care, treatment, or disposal as indicated in paragraph (b) of this section, if, in the opinion of the Administrator, the circumstances indicate the animal is in danger of harm.

(b) In the event that the APHIS official is unable to locate or notify the dealer, exhibitor, intermediate handler, carrier, or research facility as required in this section, the APHIS official shall contact a local police or other law officer to accompany him to the premises and shall provide for adequate care when necessary to alleviate the animal's suffering. If in the opinion of the Administrator, the condition of the animal(s) cannot be corrected by this temporary care, the APHIS official shall confiscate the animals.

(c) Confiscated animals may be placed, by sale or donation, with other licensees or registrants which comply with the standards and regulations and can provide proper care, or they may be euthanized. The dealer, exhibitor, intermediate handler, carrier, or research facility from whom the animals were confiscated shall bear all costs incurred in performing the placement or euthanasia activities authorized by this section.

§ 2.130 Minimum age requirements.

No dog or cat shall be delivered by any person to any carrier or intermediate handler for transportation, in commerce, or shall be transported in commerce by any person, except to a registered research facility, unless such dog or cat is at least eight (8) weeks of age and has been weaned.

§ 2.131 Handling.

(a)(1) Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause unnecessary discomfort, trauma, overheating, excessive cooling, behavioral stress, or physical harm.

(2) Physical abuse of animals or deprivation of food or water shall not be used to train, work, or otherwise handle animals.

(b)(1) During public exhibition, any animal must be handled so there is minimal risk of harm to the animal and

to the public, with sufficient distance and/or barriers between the animal and the general viewing public so as to assure the safety of animals and the public.

(2) Performing animals shall be allowed a rest period between performances at least equal to the time for one performance.

(3) Young or immature animals shall not be exposed to rough or excessive public handling or exhibited for periods of time which would be detrimental to their health or well-being.

(4) Drugs, such as tranquilizers, shall not be used to facilitate, allow, or provide for public handling of the animals.

(c)(1) Animals shall be exhibited only for periods of time and under conditions consistent with their good health and well-being.

(2) A responsible, knowledgeable, and readily identifiable employee or attendant must be present at all times during periods of public contact.

(3) At a minimum, when dangerous animals such as lions, tigers, wolves, bears, or elephants are allowed to have contact with the public, the animals must be under the direct control and supervision of a knowledgeable and experienced animal handler.

(4) If public feeding of animals is allowed, the food must be provided by the animal facility and shall be appropriate to the type of animal and its nutritional needs and diet.

§ 2.132 Procurement of random source dogs and cats, dealers.

(a) A class "B" dealer may obtain live random source dogs and cats only from:

(1) Other dealers who are licensed under the Animal Welfare Act and in accordance with the regulations in Part 2;

(2) State, county, or city owned and operated animal pounds or shelters; and

(3) A legal entity organized and operated under the laws of the State in which it is located as an animal pound or shelter, such as a humane shelter or contract pound.

(b) A class "B" dealer shall not obtain live random source dogs and cats from individuals who have not bred and raised the dogs and cats on their own premises.

(c) Live nonrandom source dogs and cats may be obtained from persons who have bred and raised the dogs and cats on their own premises, such as hobby breeders.

(d) Any person subject to the Act shall not obtain live random source dogs or cats by use of false pretenses, misrepresentation, or deception.

(e) Any licensee or registrant under the Act who also operates a private or contract animal pound or shelter shall comply with the following:

(1) The animal pound or shelter shall be located on premises that are physically separated from the licensed or registered facility. The animal housing facility of the pound or shelter shall not be adjacent to the licensed or registered facility.

(2) Accurate and complete records shall be separately maintained by the licensee or registrant and by the pound or shelter. The records shall be in accordance with §§ 2.75 and 2.76, unless the animals are lost or stray. If the animals are lost or stray, the pound or shelter records shall provide:

(i) An accurate description of the animal;

(ii) How, where, from whom, and when the dog or cat was obtained;

(iii) How long the dog or cat was held by the pound or shelter before being transferred to the dealer; and

(iv) The date the dog or cat was transferred to the dealer.

(3) Any dealer who obtains or acquires a live random source dog or cat from a private or contract pound or shelter, including a pound or shelter they operate, shall hold the dog or cat for a period of at least 10 full days, not including the day of acquisition, excluding time in transit, after acquiring the animal, and otherwise in accordance with § 2.101.

Done at Washington, D.C., this 7th day of March 1989.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 89-5612 Filed 3-9-89; 2:10 pm]

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9 CFR Part 3

[Docket No. 87-004]

Animal Welfare—Standards

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations for the humane handling, care, treatment, and transportation of dogs and cats, guinea pigs and hamsters, rabbits, and nonhuman primates. The regulations for dogs, cats, and nonhuman primates would be completely revised and rewritten. The regulations for guinea pigs, hamsters, and rabbits would be amended to revise the space requirements for primary enclosures; to amend the temperature requirements in cargo spaces in primary conveyances; and to reinstate various transportation requirements. These actions are necessary to update the regulations, to make them more consistent with other Federal regulations concerning the handling, care, treatment, and transportation of these animals, and to comply with the recent amendments to the Animal Welfare Act (7 U.S.C. 2131, *et seq.*), enacted December 23, 1985. Rewriting the regulations is also intended to make them easier to understand, thereby increasing compliance and making them more effective.

DATES: We will consider written comments postmarked or received on or before July 13, 1989.

ADDRESS: Send an original and three copies of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 1000, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 87-004. Comments received may be inspected at the APHIS Public Reading Room, Room 1141, U.S. Department of Agriculture, 14th Street and Independence Avenue, SW., Washington, DC, 8:00 a.m to 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. R.L. Crawford, Director, Animal Care Staff, REAC, APHIS, USDA, Room 268, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7833.

SUPPLEMENTARY INFORMATION:

General Background and Statutory Information

Regulations on the humane handling, care, treatment, and transportation of (1) dogs and cats, (2) guinea pigs and hamsters, (3) rabbits, and (4) nonhuman primates, are contained in 9 CFR Part 3. Subpart A contains the regulations concerning dogs and cats; Subpart B contains the regulations concerning guinea pigs and hamsters; Subpart C contains the regulations concerning rabbits; and Subpart D contains the regulations concerning nonhuman primates. The regulations in each of these Subparts include minimum standards for handling, housing, feeding, watering, sanitation, ventilation, shelter, and veterinary care. The regulations are issued and enforced by the Animal and Plant Health Inspection Service (APHIS), of the United States Department of Agriculture (USDA), under authority of the Animal Welfare

Act, as amended (the Act) (7 U.S.C. 2131, *et seq.*).

On December 23, 1985, extensive amendments to the Act were enacted (see Pub. L. 99–198. "The Food Security Act of 1985.") Among other things, the amendments direct the Secretary of Agriculture to promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors, for exercise of dogs, and for a physical environment adequate to promote the psychological well-being of nonhuman primates.

Previously Proposed Regulations

In response to the 1985 amendments to the Act, we proposed, on March 31, 1987, to revise 9 CFR Parts 1 and 2. Part 1 includes definitions of terms used throughout our regulations. Part 2 includes general requirements for licensing and registration of facilities; recordkeeping and identification of animals; holding periods and facilities; Institutional Animal Care and Use Committees; adequate veterinary care, and other areas of general concern relevant to the humane care, handling, treatment and transportation of all animals and individuals subject to our regulations. (52 FR 10292–10322).

Documents containing Parts 1 and 2, as revised in accordance with our consideration of the nearly 8,000 comments we received in response to the March 31, 1987 proposal, our ongoing consultation with the U.S. Department of Health and Human Services and other interested agencies, and our experience in enforcing the regulations, appear elsewhere in this issue of the **Federal Register**. The revised rules for Parts 1 and 2 are published for the sole purpose of soliciting comments on the narrow issue of the interrelationship of Parts 1 and 2 with the Part 3 standards we are proposing in this document. All comments on this issue should not be combined with substantive comments on the Part 3 standards and must reference docket nos. 88–013 and 88–014. We will refer to those documents at various points in our discussion of the proposed amendments to Part 3.

The revised rule for Part 2 contains provisions and procedures for allowing exceptions by research facilities in compliance with the Animal Welfare regulations, including the standards proposed in this document, when necessary for the conduct of biomedical research. Exceptions or deviations from the regulations must first be explained, reviewed, and approved in accordance with the procedures set forth in Part 2. We refer the reader to 2.30(g), 2.35(b)(3), and 2.100, published elsewhere in this issue of the **Federal Register** for these provisions.

Consultation and cooperation with other Federal departments, agencies, or instrumentalities

The amendments to the Act also direct the Secretary of Agriculture to

> Consult and cooperate with other Federal departments, agencies, or instrumentalities concerned with the welfare of animals used for research, experimentation or exhibition, or administration of statutes regulating the transportation in commerce or handling in connection therewith of any animals when establishing standards pursuant to section 2143 of this title and in carrying out the purposes of this chapter.

(Section 1757, 99 Stat. 1649, Pub. L. 99–198, amending 7 U.S.C. 2145(a))

Accordingly, we consulted with the Department of the Interior, U.S. Fish and Wildlife Service (USFWS), which regulates transportation of wild birds and animals into the United States.

The amendments also specifically direct the Secretary of Agriculture to "consult with the Secretary of Health and Human Services prior to issuance of regulations." (See § 1757, 99 Stat. 1649, Pub. L. 99–198, amending 7 U.S.C. 2145(a).) The Department of Health and Human Services, through the Public Health Service, National Institutes of Health (NIH), currently issues guidelines on the care and use of animals studied in biomedical research. The animals include dogs and cats, guinea pigs and hamsters, rabbits, and nonhuman primates. These NIH guidelines are contained in a document entitled "Guide for the Care and Use of Laboratory Animals" (NIH Guide or Guidelines).[1] The Guide is widely accepted by scientific institutions as a primary reference on animal care and use. Compliance with the NIH Guidelines is not mandatory except to obtain NIH funding, but most research laboratories in the United States do comply. While the Animal Welfare Act and regulations address a broader range of activities and facilities than the NIH Guide, Congress' intent in requiring consultation with the Department of Health and Human Services is to ensure that, whenever possible, the regulations and the NIH Guidelines are consistent:

> The Conferees expect the Secretary of Agriculture to have full responsibility for enforcement of the Animal Welfare Act. However, the Conferees also recognize that a portion of the nation's research facilities fall under regulation from more than one agency. While the legislative mandate of each agency is different, and they may regulate different aspects of animal care, it is hoped that the agencies continue an open communications to avoid conflicting regulations wherever possible or practice. [sic]

(*See* Conference Report, *Congressional Record* of December 17, 1985, at page H12422.)

We consider our mandate to consult with the Department of Health and Human Services to be extremely important. We realize that having harmonious regulations throughout the Federal government on animal welfare matters would eliminate confusion and simplify compliance for the individuals, including research institutions, subject to those regulations. However, our goal in proposing these regulations is to provide for the humane care, handling, treatment, and transportation of various animals. If we adopt regulations identical with those of other Federal Departments, but those regulations are ineffective or inadequate, then we have not met the statutory objective.

We have attempted in these proposed regulations to meet both goals wherever we have determined it is consistent with our responsibility to promote animal welfare. To achieve this, we have consulted extensively with NIH representatives concerning standards for the humane care, handling, treatment, and transportation of dogs and cats, guinea pigs and hamsters, rabbits, and nonhuman primates. We have reviewed our existing regulations and the NIH guidelines. In addition, we have considered comments raised by member agencies of the Interagency Research Animal Committee, which is comprised of federal agencies that conduct research using animals. We have also consulted with experts and professional organizations and have sought their recommendations on appropriate standards to accomplish our goal. After considering all this information, we are proposing extensive revisions to the regulations in 9 CFR Part 3, Subparts A, B, C, and D. In many cases, we are proposing regulations substantially identical to current NIH Guidelines. That is because, in these cases, we believe the NIH Guidelines are appropriate and adequate to provide for the humane care, handling, treatment, and transportation of the animals in question. In other cases, we

[1] The NIH Office for Protection from Research Risks publishes another document called the "Public Health Service Policy on Humane Care and Use of Laboratory Animals," under authority of the Health Research Extension Act of 1985 (Pub. L. 99–158, November 20, 1985). However, the regulations in that document concern mainly the use of tranquilizers and other drugs on animals being used in research, appropriate pre- and post-surgical veterinary care for animals being used in research, and the organization and operation of animal care committees. These subjects are not covered in this proposal, and we therefore do not discuss these NIH requirements in this document.

are proposing to adopt, as our regulations, standards that will provide for the humane handling and care of animals covered by the Act. We will discuss our proposed changes on a subpart-by-subpart basis.

We are proposing to revise Subparts A and D in their entirety in this document so that the regulations are complete and easier to read. However, we are not providing an explanation for nonsubstantive revisions.

Subpart A—Dogs and Cats

Regulations for humane handling, care, treatment, and transportation of dogs and cats are contained in 9 CFR Part 3, Subpart A. These regulations include minimum standards for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperature, veterinary care, and transportation.

It should be noted that the proposed regulations apply only to live dogs and cats, unless indicated otherwise.

We are proposing to revise and rewrite the current regulations based on our experience administering them. We are also proposing to amend our regulations to add requirements for the exercise of dogs. This is specifically required by the 1985 amendments to the Act. (See Section 1752, 99 Stat. 1645, Pub. L. 99–198, amending Section 13 of the Act). We discuss each topic covered in our proposed regulations below.

Housing Facilities and Operating Standards

Current §§ 3.1 through 3.3 provide requirements for facilities used to house dogs and cats. Current § 3.1, "Facilities, general," contains regulations pertaining to housing facilities of any kind. It is followed by current § 3.2, "Facilities, indoor," and § 3.3, "Facilities, outdoor." We are proposing to amend these sections to provide for an environment that better promotes the health, comfort, and well-being of dogs and cats. We are also proposing to add sections that provide regulations specifically governing two other types of facilities used to house dogs and cats, sheltered housing facilities, and mobile or traveling housing facilities. The term "sheltered housing facility" is defined in Part 1, published elsewhere in this issue of the **Federal Register**, as "a housing facility which provides the animals with shelter; protection from the elements; and protection from temperature extremes at all times. A sheltered housing facility may consist of pens or runs totally enclosed in a barn or building, or of connecting inside/outside runs or pens with the inside pens in a totally enclosed building." The term "mobile or traveling housing facility" is also included in Part 1, and is defined as "a transporting vehicle such as a truck, trailer, or railway car, used to house animals while traveling for exhibition or public education purposes."

Some of the regulations we are proposing for housing facilities are applicable to housing facilities of any kind. As in the current regulations, these standards of general applicability would be included in one section, proposed § 3.1. that would also include many of the provisions in current § 3.1. Additionally, we are proposing amendments to the current regulations that are specific to particular types of housing facilities, and are including those provisions in separate sections of the proposed regulations. In some cases where the current regulations would be unchanged in substance, we have made wording changes to clarify the intent of the regulations.

Housing facilities, general

In proposed § 3.1(b), we are proposing to add the requirements that a dealer's or exhibitor's housing facilities be physically separated from any other business. When more than one dealer maintains facilities on the premises, it can be difficult to determine which dealer is responsible for which animals and for the overall conditions. To avoid this difficulty, we are proposing to require that housing facilities other than those maintained by research facilities and federal research facilities be separated from other businesses. This can be done by using a security fence or by conducting each business in a separate building. For example, if a security fence is used, it would have to be constructed so that it prevents unauthorized humans, and animals the size of dogs, skunks, and raccoons, from going through or under it. We are not imposing this requirement on research facilities because they are often part of a larger sponsoring establishment, such as a university or pharmaceutical company, and responsibility for animal and site conditions rests with that establishment. Therefore, we have not encountered the enforcement difficulties noted above with research facilities.

Proposed § 3.1(b) would also require that housing facilities and areas used for storing animal food and bedding be kept free of any accumulation of trash, weeds, and discarded material, in order to prevent an unsanitary condition and problems with diseases, pests, and odors. The need for orderliness applies particularly to the areas where animals are maintained in the housing facilities. These areas would have to be kept free of clutter, including equipment, furniture, and stored material, and materials not necessary for proper husbandry practices.

We are proposing to include requirements concerning housing facility surfaces that are common to all types of facilities in proposed § 3.1(c). We are proposing to include requirements specific to particular types of facilities in separate sections. In § 3.1(c)(1), we propose to require that the surfaces of housing facilities either be easily cleaned and sanitized, or be removable or replaceable when worn or soiled. These provisions would also apply to houses, dens, and other furniture-type fixtures or objects within the facility.

Proposed § 3.1(c)(1) would also require that any surfaces that come in contact with dogs and cats be free of jagged edges or sharp points that might injure the animals, as well as rust that prevents the required cleaning and sanitization. Because we recognize that as long as water is used to clean animal areas, metal parts will rust, we would allow rust on metal surfaces, as long as it does not reduce structural strength or interfere with proper cleaning and sanitizing.

Section 3.1(c)(2) would require that all surfaces be maintained on a regular basis and that surfaces that cannot be easily cleaned and sanitized be replaced when worn or soiled.

Section 3.1(c)(3) would require that hard surfaces that come in contact with dogs or cats be cleaned daily and sanitized at least every two weeks, and as often as necessary to prevent any accumulation of excreta and disease hazards. Section 3.10(b) provides for various methods of sanitizing primary enclosures and food and water receptacles. Because these methods are effective in general for sanitization of hard surfaces that cats and dogs come in contact with, any of them could be used for the sanitization required by § 3.1(c). Floors made of dirt, sand, gravel, grass, or other similar material would have to be raked and spot-cleaned daily, since sanitization is not practicable, and the flooring material would have to be replaced if raking and spot-cleaning are not sufficient to eliminate odors, diseases, pests, insects, or vermin infestation. All other surfaces would have to be cleaned daily and sanitized when necessary to satisfy generally accepted professional and husbandry practices.

In the current regulations, § 3.1(b) provides regulations for water and electric power. It specifies that reliable and adequate water and electric power must be made available "if required to comply with other provisions of this

subpart." In this proposed rule, provisions concerning water and electric power are set forth in § 3.1(d). We are proposing there to eliminate the qualifying statement cited above, and to *require* that all facilities have reliable and adequate electric power and mechanically pressurized potable running water for the dogs' and cats' drinking needs, for cleaning, and for carrying out other husbandry requirements. Based on our inspections of dealer, exhibitor, and research facilities, we believe that dog and cat facilities subject to the regulations cannot be properly cleaned and maintained without electric power and potable water under pressure. We would require that a pressurized water system be used to ensure that the water supply is of sufficient quantity and availability to meet the needs of the animals and the facility.

We are proposing in § 3.1(e) to expand the regulations in current § 3.1(c) concerning proper storage of food and bedding supplies. We would retain the requirements that food and bedding be stored so as to protect them from vermin infestation or contamination, and that perishable food be refrigerated. Additionally, we are proposing requirements to ensure further the quality of the food and bedding used by animals, and therefore of the area in which the animals are housed. We would specify that supplies of food and bedding be stored in containers to protect the supplies from spoilage as well as from infestation and contamination. The supplies would have to be stored off the floor and away from the walls, to allow cleaning around and underneath them. All food would have to be stored so as to prevent contamination or deterioration of its nutritive value. Open supplies of food and bedding would have to be stored in leakproof containers with tightly fitting lids. Substances toxic to dogs and cats would not be allowed to be stored in animal areas or in food storage and preparation areas.

Proposed § 3.1(f) would continue to require that housing facilities provide for removal and disposal of animal and food wastes, bedding, dead animals, and debris, as provided in current § 3.1(d). We are proposing to clarify this requirement so that it includes all fluid wastes and to include a provision that arrangements must be made for removal and disposal of wastes at least daily, and more often if necessary. The proposed regulations would also require that trash containers be leakproof and be tightly closed when not in use, and that no forms of animal waste, including dead animals, be kept in food and animal areas.

Requirements for drainage are currently contained in §§ 3.2(e) and 3.3(d), under the sections concerning indoor facilities and outdoor facilities, respectively. Since all types of animal housing facilities, including our proposed categories of sheltered housing facilities, and mobile or traveling housing facilities, must have some way of disposing of waste and liquids, we would consolidate all drainage and waste disposal requirements in proposed § 3.1(f).

Both current §§ 3.2(e) and 3.3(d) require that a suitable method of eliminating excess water be provided. That requirement would be retained and expanded to pertain to sheltered and to mobile or traveling housing facilities as well. Current § 3.2(e) requires that any drains used be properly constructed and kept in good repair to guard against foul odors. Additionally, where closed drainage facilities are used, they must be equipped with traps and be installed so that they prevent any backup of sewage onto the floor. Those requirements would be retained and expanded for indoor facilities, and the proposed expanded provisions would also apply to other types of facilities where such drainage is appropriate. We would require that disposal and drainage systems also minimize vermin and pest infestation, and disease hazards. As part of this safeguard, we would require that any sump or settlement pond, or similar system for drainage and animal waste disposal, be located an adequate distance from the animal area of the housing facility. We would also require that puddles of water in animal areas be promptly mopped up or drained so that the animals stay dry.

The requirement in current § 3.1(e) that washing facilities be available to animal caretakers for their own cleanliness would be retained and would appear in proposed § 3.1(g).

Categories of Housing Facilities

The current regulations specify two kinds of housing facilities, "indoor" and "outdoor." These terms are defined in Part 1 of the Animal Welfare regulations, published elsewhere in this issue of the **Federal Register.** (*See* companion docket no. 88–013). Briefly, an indoor housing facility is defined as an enclosed structure or building with environmental controls that is used to house animals. An outdoor housing facility is defined as a structure, building, land, or premises, used to house animals, that cannot be temperature controlled and that does not have a completely enclosed temperature-controlled shelter. We recognize that these two categories of housing facilities do not cover all of the wide variety of facilities used to house dogs and cats. For example, certain facilities, such as those in which animals have access to pens in a building, but also have access from their pens to outside runs, fall somewhere between "indoor" or "outdoor" facilities. Another "grey area" involves traveling animal shows. In order to clarify the intent and applicability of the regulations, we are proposing to add provisions for two additional types of housing facilities that are used to house dogs and cats: "sheltered housing facilities," and "mobile or traveling housing facilities." A sheltered housing facility is defined in Part 1 of the regulations to mean a facility that provides animals with shelter and protection from the elements and temperature extremes at all times, such as a building with a connecting inside/outside run or pen. A mobile or traveling housing facility is defined in Part 1 to mean a transporting vehicle such as a truck, trailer, or railway car, used to house animals while traveling for exhibition or public education purposes. (*See* companion docket no. 88–013, published elsewhere in this issue of the **Federal Register.**)

Temperatures in Housing Facilities

Enclosed housing facilities—that is, indoor facilities, the sheltered portion of sheltered housing facilities, and mobile or traveling facilities—would be required to provide heating, cooling, and ventilation for the health, comfort, and well-being of dogs and cats housed there. The heating and cooling requirements would be set forth for each of the above categories in §§ 3.2(a), 3.3(a), and 3.5(a) respectively. The ventilation requirements would be set forth in §§ 3.2(b), 3.3(b), and 3.5(b) respectively.

In establishing minimum temperatures for these facilities, the proposed regulations take into account whether a particular dog or cat housed there is acclimated to relatively low temperatures, and whether for some other reason, either because of breed, age, or condition, a dog or cat should not be subjected to certain low temperatures. In § 3.2(a) of the current regulations for indoor facilities, the minimum temperature allowed is 50 °F for all dogs and cats in those facilities that are not acclimated to lower temperatures. We are proposing that in indoor, sheltered, and mobile or traveling housing facilties, the minimum temperature allowed continue to be 50

°F (10 °C) for dogs or cats not acclimated to lower temperatures. Because some dogs cannot be acclimated to lower temperatures, we would also apply the 50 °F minimum to breeds of dogs or cats that cannot tolerate lower temperature without stress and discomfort (e.g., short-haired breeds such as beagles, greyhounds, and Doberman), and to dogs and cats that are sick, aged, young, or infirm. The minimum temperature for all other dogs and cats would be 35 °F (1.7 °C), except in indoor facilities, where the minimum temperature for all other dogs and cats would be 45 °F (7.2 °C)

In the current regulations, there is no maximum temperature specified for indoor housing facilities, although auxiliary ventilation is required when the temperature rises to or above 85 °F (29.5 °C). In this proposed rule, we establish a maximum temperature of 95 °F (35 °C) for indoor facilities, mobile or traveling facilities, and the sheltered part of sheltered housing facilities, when those facilities contain dogs or cats. For each of those categories of shelters, auxiliary ventilation, such as fans or air conditioning, would have to be used when the temperature rises to or above 85 °F (29.5 °C).

Because outdoor facilities cannot be temperature-controlled, we believe it is necessary to judge a dog's or cat's suitability for outdoor housing on an individual basis. As provided in proposed § 3.4(4)(1), a dog or cat could not be kept in an outdoor facility if (1) it is not acclimated to the temperatures prevalent in the area or region where the facility is located; (2) it is of a breed that cannot tolerate the prevalent temperatures of the area without stress or discomfort (such as short-haired breeds in cold climates); or (3) it is aged, young, sick or infirm. We recognize that in some situations, particularly in the case of dogs or cats obtained from pounds, it will not be known whether animal has been acclimated to prevailing temperatures. Therefore, in proposed § 3.4(a)(2), we provide that if a dog's or cat's acclimation status is unknown, it must not be kept in an outdoor facility in any month in which, during the preceding 5 years, the temperature at the facility has been less than 35 °F (1.7 °C).

Ventilation of Housing Facilities

The requirements for ventilation of indoor housing facilities that are set forth in § 3.2(b) of the current regulations would be retained in the proposal, and would be extended to apply to all sheltered portions of sheltered, and mobile or traveling, housing facilities to provide for the health, comfort, and well-being of dogs and cats. Based on our inspections of dealer, exhibitor, and research facilities, we are proposing to add (1) that ventilation must also be provided to minimize ammonia levels in these housing facilities; (2) that ventilation in mobile or traveling facilities must minimize exhaust fumes; and (3) that in indoor housing facilities, the relative humidity must be maintained between 30 and 70 percent. Although the 30–70 percent range would apply to all dogs and cats, we expect generally accepted professional and husbandry practices to be followed in providing humidity levels appropriate to particular breeds of dogs and cats. The 30–70 percent range corresponds to the recommendations contained in the NIH Guide. We are not proposing to require that precise humidity levels be maintained in sheltered housing facilities or mobile or traveling facilities. The configuration of many sheltered facilities makes humidity control impracticable, and mobile or traveling housing facilities may travel into many different parts of the United States, with varying levels of humidity.

Lighting in Housing Facilities

The proposed regulations would retain the requirement in § 3.2(c) of the current regulations that indoor housing facilities have ample light to permit routine cleaning and inspection. We are proposing to extend this requirement to all of the enclosed housing facilities included in the proposed regulations. We are also proposing to require in each case that either natural or artificial light be provided for at least 8 hours each day, corresponding to the natural period of daylight. Our experience inspecting licensees' and registrants' facilities has shown us that in the past some licensees and registrants have kept dogs and cats in darkened rooms throughout most of the day. In the case of indoor housing facilities and mobile or traveling housing facilities, we would require that if only artifical light, such as fluorescent light, is used, it must provide full-spectrum illumination. Sheltered facilities, by their nature, allow the animals access to natural light, so the requirement for full-spectrum illumination would not be necessary for those facilities. Also, we would retain the requirement in the current regulations for indoor facilities that primary enclosures be placed so as not to expose to the animals in them to excessive light, and we would extend that requirement to sheltered enclosures. An example of excessive light would be a situation where an animal is housed in the top cage of a stack of cages, near a lighting fixture.

Specific Provisions for Indoor Housing Facilities

Section 3.2(d) of the current regulations, regarding the interior surfaces of indoor housing facilities, requires that those surfaces be substantially impervious to moisture and readily sanitized. In § 3.2(d) of the proposed regulations, we would retain the requirement that all surfaces be impervious to moisture, but would make an exception in the case of ceilings that are replaceable. An example of this would be a suspended ceiling with replaceable panels. The proposed requirements concerning interior surfaces are more stringent for indoor housing facilities than for any other type of facility. Only in indoor facilities, for example, would ceilings have to be either impervious to moisture or replaceable. This is because indoor facilities generally operate on one ventilation system, and any disease organisms or excessive odors that occur in the facility might spread throughout the facility, requiring a thorough cleaning or replacement of all interior surfaces.

Specific Provision for Sheltered Housing Facilities

In proposed § 3.3(d) regarding sheltered housing facilities, we would require that dogs and cats be provided with adequate shelter and protection from the elements.

In order to maintain sanitary conditions in sheltered housing facilities, we would estabish the following requirements in § 3.3(e). The following areas would have to be impervious to moisture: (1) indoor floor areas in contact with the animals; (2) outdoor floor areas not exposed to the direct sun or made of a hard material such as wire, wood, metal, or concrete, in contact with the animals; and (3) all walls, boxes, houses, dens, and other surfaces in contact with the animals. Outside floor areas in contact with the animals and exposed to the direct sun could consist of compacted earth, sand, gravel, or grass.

Specific Provisions for Outdoor Housing Facilities

The intent of § 3.3 of the current regulations is to provide adequate standards for the care of animals housed outdoors. However, our inspections of dealers' and exhibitors' facilities in climates with temperature extremes have indicated that some licensees are not meeting what we believe should be

minimum standards for the treatment of dogs and cats. Specifically, we believe that the regulations need to be made more stringent regarding the types of dogs and cats that can be kept outdoors, and regarding what shelter is necessary for dogs and cats kept outdoors. Therefore we are proposing to revise the current requirements for outdoor facilities, to make them more clearly defined and more stringent.

We have discussed earlier in this document the categories of dogs and cats that must not be kept in outdoor housing facilities. With regard to the type of shelter required for dogs and cats housed outdoors, we believe that the current regulations should be expanded to specify what is necessary for better and more humane treatment of the dogs and cats. In essence, the current regulations require that dogs and cats be provided with sufficient shade to protect them from the direct rays of the sun, shelter to keep them dry during rain or snow, and shelter when the atmospheric temperature falls below 50 °F. (10 °C). Additionally, bedding or some other protection is required when the ambient temperature falls below that to which the dog or cat is acclimated.

In § 3.4(b) of this proposed rule, we require that all outdoor facilities housing dogs or cats include a shelter structure that is accessible to all animals in the facility, and that is large enough to allow all animals in the structure to sit, stand, and lie in a normal manner, and to turn about freely. As proposed in § 3.4(d), the shelter structure would have to: (1) Provide adequate shelter and protection from the cold and heat; (2) be protected from the direct rays of the sun and the direct effect of wind, rain, or snow; (3) have a wind break and a rain break at its entrance; and (4) contain clean dry, bedding material. We are also proposing in § 3.4(b) that in addition to the shelter structure, there would have to be a separate outside area of shade provided, large enough to contain all the animals at one time and to protect them from the direct rays of the sun. This shaded area would give the animals relief on hot days, when they would be unlikely to seek shelter in an unventilated structure.

In proposed § 3.4(c), we would require that all building surfaces that are in contact with dogs or cats in outdoor housing facilities be impervious to moisture. Metal barrels, old refrigerators or freezers, and the like would not be permitted as shelter structures. The floors of outdoor housing facilities could be of compacted earth, sand, gravel, or grass, but would have to be kept clean.

Primary Enclosures

We are proposing to amend current § 3.4, "Primary enclosures." The current section provides general requirements for construction and maintenance of primary enclosures, uniform space requirements for each dog or cat housed in a primary enclosure, and provisions regarding litter and resting surfaces for cats and the tethering of dogs on chains. We are proposing to expand the current general requirements, to add some new requirements, and to clarify the existing requirements in accordance with the intent of the amendments to the Act.

The proposed regulations regarding primary enclosures, contained in proposed § 3.6, would require that all primary enclosures meet certain minimum requirements that we believe are necessary for the safety and well-being of dogs and cats. A primary enclosure is defined in Part 1 as "any structure or device used to restrict an animal to a limited amount of space, such as a room, pen, run, cage, compartment, pool, hutch, or tether." Included among the primary enclosures subject to the regulations would be those used by circuses, carnivals, traveling zoos, educational exhibits, and other traveling animal acts and shows. Proposed § 3.6(a) would continue to require that primary enclosures be structurally sound and maintained in good repair to protect the animals from injury, to contain them, and to keep predators out. We would also require that the primary enclosure keep unauthorized humans out. We would continue to require that the primary enclosures enable the animals to remain dry and clean, that they provide the animals with convenient access to food and water, that they provide sufficient space for the dogs and cats to have normal freedom of movement, and that their floors be constructed in a manner that protects the animals from injury. We would add the requirements that the primary enclosures be constructed without sharp points or edges, and that they provide sufficient shade to the animals in the enclosures and protect them from temperature extremes and other weather conditions that might be uncomfortable or hazardous to the animals. We would also require that the primary enclosures be easily cleaned and sanitized.

However, if the floors of primary enclosures consist of earth, sand, gravel, or grass, we would require that they be replaceable, rather than easily cleaned and sanitized.

Additional Primary Enclosure Requirements for Cats

We are proposing to change the space requirements for cats. In general, the proposed regulations would base how much space a cat should have on the animal's weight, and whether it is a nursing mother. The space requirements in §§ 3.4(b) (1) and (3) of the current regulations are uniform for all cats, regardless of size, and require that each cat be given a minimum of 2.5 ft^2, with room to turn about freely, and to easily stand, sit, and lie in a confortable normal position. We believe, based on our inspections of research facilities, that the current minimum space requirements should be increased for all cats. Additionally, because the weight of a cat is a good indicator of its overall size, we believe that floor space requirements should distinguish between cats of different weights. Our proposed standards would provide cats with the space we believe is necessary and at the same time make our regulations correspond to the NIH Guide for the Care and Use of Laboratory Animals. In proposed § 3.6(b)(1), we would require that weaned cats weighing 8.8 lbs (4 kg) or less be provided with at least 3.0 ft^2 (0.28 m^2) of floor space, and that cats weighing over 8.8 lbs (4 kg) be provided with a minimum of 4.0 ft^2 (0.37 m^2) of floor space. Additionally, we would require that each queen with nursing kitten be provided with an additional amount of floor space, equivalent to at least 5 percent of her minimum required floor space for each nursing kittens in the litter. For example, five nursing kittens would require a 25-percent increase and 10 nursing kittens would require a 50-percent increase. The minimum floor space required would be exclusive of any food, water, or litter pans, and the height of the primary enclosure for cats would have to be at least 24 inches (60.96 cm).

All cats housed in the same primary enclosure would have to be compatible. The requirement in current § 3.4(b)(3) that no more than 12 adult nonconditioned cats be housed in the same primary enclosure would be retained and set forth in proposed § 3.6(b)(2). In addition, the following restrictions would apply: queens in heat could not be housed in the same primary enclosure with sexually mature males, except for breeding; queens with litters and kittens under 4 months of age could not be housed in the same primary enclosure with any other adult cats, except when maintained in a breeding colony; and cats with a vicious or

aggressive disposition would have to be housed separately.

In § 3.6(b)(3), we are proposing to retain the current requirement that a receptacle with litter be provided to contain excreta.

The current standards for cats in § 3.4(a)(2)(ii) state that there must be a solid resting surface in each primary enclosure that will comfortably hold all occupants at the same time, and that the resting surface be elevated if the enclosure holds two or more cats. We are proposing to require in § 3.6(b)(4) that all such resting surfaces be elevated, even if only one cat is in the enclosure, and to clarify that the resting surfaces not be counted as part of the minimum floor space. The resting surfaces would have to be impervious to moisture, and would have to be either easily cleaned and sanitized, or easily replaceable when soiled or worn.

We are proposing to provide, in § 3.6(b)(5), that cats in mobile or traveling shows or acts may be kept, while the show or act is traveling from one temporary location to another, in transport containers that comply with all requirements of § 3.14 of this subpart other than the marking requirements in § 3.14(a)(6). When the show or act is not traveling, the cats would have to be placed in primary enclosures that meet the minimum requirements of § 3.6. Mobile or traveling shows and acts normally remain in one location for several days and then move to another location, with the movement taking a day or less. Because the animals are less subject to injury in smaller enclosures while traveling, we would allow the use of transport cages during this time. When not traveling, however, the cats would have to be placed in primary enclosures that comply with the minimum space requirements and other requirements of § 3.6.

Additional Primary Enclosure Requirements for Dogs

In proposed § 3.6(c), we would retain the formulas in § 3.4(b)(2) of the current regulations for calculating the floor space for dogs [(length of dog in inches + 6) × (length of dog in inches +6) = required square inches of floor space; required square inches/144 = required square feet]. Because of the great variation in size and body conformation among the various species of dogs, we believe the present formula for calculating space based on body length is more appropriate than a formula based on the weight of the dog. Space requirements based on weight do not allow for the differences in body conformation among different breeds of dogs, such as bulldogs and whippets or greyhounds. Space requirements based on body length do allow for differences in body conformation and would therefore be retained as a more appropriate method for determining minimum space requirements. We are also proposing the require that the minimum height of a primary enclosure be at least 6 inches above the highest point of the body (normally the ears) of the tallest dog in the enclosure when standing in a normal position.

As with cats, nursing mothers would have to be provided with additional space. In proposed § 3.6(c)(1)(ii), we would require that each bitch with nursing puppies be provided with an additional amount of floor space, equal to 5 percent of her minimum floor space, for each nursing puppy in the litter.

In § 3.4(b)(2)(ii) of the current regulations, requirements are set forth for dog houses with chains used as primary enclosures for dogs kept outdoors. In § 3.6(c)(2) of the proposed regulations, we would expand those regulations and would apply the expanded regulations to apply to dogs that are tethered by any means, and not just by chains. We would retain the current requirement that a dog that is tethered be kept from being entangled, and would add the requirements that the dog not be able to come into physical contact with other dogs in the housing facility, and be able to roam to the full range of the tether. We would retain the current requirement that the tether be of the type commonly used for the size dog involved, and that the tether be attached to the dog by a well-fitted collar. Additionally, we propose to explicitly require that the collar must not cause trauma or injury to the dog. The proposed regulations include the following examples of types of collars that would be prohibited: collars made of wire, flat chains, chains with sharp edges, and chains with rusty or nonuniform links. As in the current regulations, the tether would have to be at least three times the length of the dog as measured from the tip of its nose to the base of its tail. We would require that the tether be attached to the front of the dog's shelter structure or to a post in front of the shelter structure, and that it allow the dog convenient access to the shelter structure and to food and water containers.

We are also proposing that dog housing area where chains or tethers are used must be enclosed by a perimeter fence at least 6 feet in height, so as to protect the dogs, to contain them, and to keep animals that size of dogs, racoons, and skunks from going through or under it.

All dogs housed in the same primary enclosure would have to be compatible. The provision in § 3.4(b)(2) limiting to 12 the number of nonconditioned adult dogs permitted to be housed in the same primary enclosure would be retained in proposed § 3.6(c)(3). Additionally, that proposed paragraph would contain the following provisions: bitches in heat must not be housed in the same primary enclosure with sexually mature males, except for breeding; bitches with litters must not be housed in the same primary enclosure with other adult dogs, and puppies under 4 months of age must not be housed in the same primary enclosure with adult dogs, except when maintained in a breeding colony; and dogs with a vicious or aggressive disposition must be housed separately.

We are also proposing to provide, in § 3.6(c)(4), that dogs in mobile or traveling shows or acts may be kept, while the show or act is being transported from one temporary location to another, in transport containers that comply with all requirements of proposed § 3.14 of this subpart, other than the marking requirements in § 3.14(a)(6). When the show or act is not traveling, the dogs would have to be placed in primary enclosures that meet the minimum requirements of § 3.6. Mobile or traveling shows and acts normally remain in one location for several days and then move to another location, with the movement taking a day or less. Because the animals are less subject to injury in smaller enclosures while traveling, we would allow the use of transport cages during this time. When stopped and not traveling, however, the dogs must be placed in primary enclosures that comply with the minimum space and other requirements of § 3.6. As explained above, we are also proposing similar provisions regarding cats in mobile or traveling shows or acts.

Variance

We understand that the proposed minimum space requirements for dogs and cats might require persons subject to the Animal Welfare regulations to rebuild or remodel their facilities and to expend previously unanticipated and unbudgeted monies for new primary enclosures and fixtures. In some instances, major structural modifications might be required to satisfy the proposed space requirements. Until the necessary adjustments were made, many registrants and licensees would not be in compliance with the proposed requirements.

In cases where the effective date of the regulations would not coincide with

a facility's fiscal year, we are aware that budget planning and funding procedures for the next fiscal year would take some time. Once funds have been appropriated, facilities would require additional time to make the necessary space modifications. To allow facilities sufficient time to conform with the proposed minimum space requirements, we are proposing to include a mechanism for issuing variances to eligible persons. This mechanism would be similar to that already in place for licensees and registrants in Subpart E—"Specifications for the Humane Handling, Care, Treatment and Transportation of Marine Mammals."

A "variance" would be issued, in writing, by the Administrator of APHIS, and would allow an eligible registrant or licensee to continue operating even though not fully in compliance with the minimum space requirements for dogs and cats, including minimum space requirements for the exercise of dogs.

The variance would be limited in scope both as to time and to the primary enclosures covered by it, and would specify the portions of the applicant's facilities to which it applied.

Registrants and licensees maintaining or handling dogs or cats, having dogs or cats on their premises or under their control or supervision, and not complying with the minimum space requirements proposed in § 3.6, could apply for a variance. Facilities that are under construction or that are in the design or preliminary construction stages on the date these regulations become effective would not be eligible for a variance, since they could adapt their construction to comply with them. However, a facility that is so nearly complete that it would require substantial modification at a previously unbudgeted and significant cost to bring it into compliance would be eligible for a variance.

A variance could be granted, at the sole discretion of the Administrator, for up to 2 years. We believe that this would allow sufficient time for a registrant or licensee to raise the necessary funds and to contract for the required work, as well as to purchase whatever fixtures or equipment were necessary for it to comply with the minimum space requirements. One extension of up to 1 year could be granted by the Administrator if he or she determined that it was necessary, based upon the facts presented in the application for extension. The extension would be granted if justified due to unforeseen situations that prevented full compliance during the variance period. As an example, unforeseen circumstances for research facilities could be nonallocation of public funds to make the necessary expenditures.

An application for a variance would be required within 60 days of the effective date of these regulations and would have to be in writing. According to the proposed regulations, it must list, in detail, specific reasons why the variance was being requested, and each of the minimum space requirements the facility cannot meet. It must identify the species and number of dogs and cats that would be affected by the variance, and must state the amount of time necessary for the applicant to come into compliance and the estimated cost of compliance.

We are proposing to require a statement from the attending veterinarian concerning the age and health status of the dogs and cats affected by the variance, and addressing whether granting the variance would be detrimental to the affected dogs and cats.

As is presently the case for marine mammals, the Administrator could require the submission of an outside independent expert report, if the Administrator believes it would assist him or her in determining whether the granting of a variance would be detrimental to the health and well-being of the affected dogs and cats. The applicant would bear the cost of the expert report.

The Administrator would grant an application for a variance if he or she determined it was justified, or would deny it if he or she determined that it was not justified or that granting it would be detrimental to the health and well-being of the dogs and cats affected. The grant or denial would be in writing. The applicant could request that the Administrator reconsider his or her decision to deny an application, in accordance with the requirements of § 3.6(d)(4). Similarly, a request for an extension would be granted by the Administrator if he or she determined that it was justified, or denied if he or she determined that it was not justified or that granting it would be detrimental to the health and well-being of the dogs and cats affected. The grant or denial of the extension would also be in writing. The applicant could request that the Administrator reconsider his or her decision to deny an application for an extension, in accordance with the requirements of § 3.6(d)(5). If the extension were granted upon reconsideration, it would be retroactive to the termination date of the initial variance.

Variances would be revocable for bad faith, such as a false representation in the initial application or in the request for extension. They could also be revoked if the purposes for which they were issued were not being carried out, or if detrimental to the health and well-being of the dogs or cats affected.

Exercise and Socialization for Dogs

In accordance with the 1985 amendments to the Act, we have developed standards for the exercise and socialization of dogs and are proposing a new § 3.7, titled "Exercise and socialization for dogs." This section would be divided into four subsections: social contact while being housed, held, or maintained; release for exercise and socialization; methods and period of exercise; and exemptions from exercise.

Social Contact for Dogs

Under the provisions for social contact in proposed § 3.7(a), we would require that all dogs housed, held or maintained by any dealer, exhibitor, or research facility be maintained in compatible groups. We are proposing exceptions to this provision however, for certain situations that involve either the provisions of an animal care and use procedure approved by a research facility's Committee, or the health and well-being of the dogs. Because of the social nature of dogs, we are also proposing to require, with similar exceptions, that all dogs be able to see and hear other dogs. If a dog is unable to see and hear other dogs simply because it is the only dog in a facility, we would require that it receive positive physical contact with humans at least once a day. "Positive physical contact" is defined in Part 1 as "petting, stroking, or other touching, which is beneficial to the well-being of the animal." (*See* companion docket no. 88–013, published elsewhere in this issue of the **Federal Register.**) This contact would have to total at least 60 minutes each day and could be given in one or more periods.

Release for Exercise and Socialization

Provisions for the release of dogs for exercise and socialization are set forth in proposed § 3.7(b). With certain exceptions that are explained below, we are proposing to require that the following categories of dogs, if housed, held, or maintained by any dealer, exhibitor, or research facility, be released at least once a day for exercise and socialization: (1) Dogs that are kept in individual cages or that are kept individually in pens or runs that provide less than four times the space required for that dog, and that do not allow visual and physical contact with other dogs; and (2) dogs housed, held, or maintained in groups that are not provided with the

greater of 80 sq. ft. of space or 150 percent of the minimum space required for all dogs in the group. In some cases, a dog could be physically restricted from other dogs and still receive what we consider adequate social contact with other dogs. For instance, the required socialization could include a dog's being able to nuzzle another dog through a chain link fence.

However, dogs housed, held, or maintained individually would not have to be released if they are kept in pens or runs that provide at least four times the required space for that dog, and that allow the dogs visual and physical contact with other dogs. Also, in certain cases, the approved animal care and use procedure might prohibit the dogs' release for exercise and socialization. In those cases, the dogs would have to be maintained in pens or runs that provide each dog with at least twice the minimum floor space set forth in § 3.6(c)(1) of the proposed subpart with regard to primary enclosures. The exercise area would have to be at least 80 square feet, except that the area would have to provide each dog with at least twice the minimum floor space required by proposed § 3.6(c)(1).

Dogs housed, held, or maintained in groups would not have to be released for exercise if the dogs are maintained in pens or runs that provide the greater of 80 square feet or 150 percent of the space each dog would require under proposed § 3.6(c)(1) if maintained separately. The exercise area would have to be the greater of 80 square feet or 150 percent of the minimum space requirement in § 3.6(c)(1), as calculated for all dogs in the exercise area. For example, the following calculations might be used in the case of six beagles housed together. A 28-inch beagle would require a minimum floor space of 8 square feet. Therefore, 150 percent of six times the minimum per-beagle requirement of 8 square feet is 72 square feet. Since that is less than 80 square feet, the larger space would be required. We believe that 80 square feet is a generally accepted minimum standard, based on comments we received from interested parties in response to a request for information.

The exercise period for all dogs that are released for exercise would have to be at least 30 minutes each day, and could be provided in one or more release periods. The consensus of APHIS veterinarians with training and experience in the care of dogs is that 30 minutes of daily exercise is a reasonable minimum for maintenance of a dog's health and well-being.

Methods of Exercise

Proposed § 3.7(c) provides that the method or type of exercise or release period used may be determined by the attending veterinarian and may consist of one or more methods. Suitable methods would include: walking on a leash; release into a room; release into a run or pen with more than 80 square feet of floor space; or some other similar type of arrangement. While forced exercise methods such as treadmills, carousels, or swimming would not be prohibited, they would not be considered acceptable forms of exercise for the release periods. Congressional intent with regard to the Act was to give dogs an *opportunity* for exercise, not to *force* them to exercise.

Record of Exercise

Under proposed § 3.7(d), the licensee or registrant would have to keep a record of each dog's release for exercise. These records would be subject to APHIS inspection.

Exemptions from Exercise

We recognize that certain situations will require an immediate response from facility personnel when a dog's welfare requires that it be provided less than the minimum standards for release for exercise. We are therefore including a provision in proposed § 3.7(e) that would authorize an attending veterinarian to exempt or restrict a particular dog from its required exercise and social release period, if he or she determines that it is necessary to do so for the dog's health, condition, or well-being. The exemption would have to be recorded by the attending veterinarian, who would be required to review the grant of exemption at least every 30 days to determine if it is still warranted.

Feeding

In proposed § 3.8(a), concerning feeding requirements for dogs and cats, we are proposing to make minor changes to the feeding requirements in current § 3.5(a). In addition to the current provisions, we would require that food given to a dog or cat be appropriate for the animal's age.

We are proposing to make minor additions in § 3.8(b) to clarify that food receptacles must be used for dogs and cats, and must be located so as to minimize contamination by pests as well as by excreta, and so as to be protected from rain or snow. Feeding pans would either have to be made of a durable material that can be easily cleaned and sanitized, or be disposable and discarded after each use. We are proposing to require that food containers that are not discarded be cleaned daily and be sanitized before being used to feed a different dog or cat or social grouping of dogs or cats, and, as currently required, be sanitized at least once every two weeks. Self-feeders for the feeding of dry food would have to be cleaned and sanitized regularly. Measures would have to be taken to prevent molding, deterioration, and caking of the food. Any of the sanitization methods allowed in proposed § 3.10(b)(3) could be used for the sanitization required in proposed § 3.8.

Watering

Currently, § 3.6 contains provisions for offering liquids to dogs and cats and for the cleaning and disinfection of watering receptacles. Section 3.9 of the proposed rule would continue to require that potable water be offered at least twice daily, if it is not continually available, and would add the requirement that water receptacles be sanitized before being used to water a different dog or cat or social grouping of dogs or cats.

Cleaning of Primary Enclosures

We are proposing to revise and reword the provisions in current § 3.7, and to include them in proposed § 3.10, to clarify the intended requirements for sanitation and other forms of hygiene. The revised section would be titled "Cleaning, Sanitization, Housekeeping, and Pest Control."

Currently, § 3.7(a) requires that excreta must be removed from a primary enclosure "as often as necessary to prevent contamination of the dogs or cats contained therein and to reduce disease hazards and odors." This wording has resulted in differences of opinion between inspectors and regulated persons as to what constitutes "as often as necessary." Therefore, in § 3.10(a), we are proposing to change this wording to require that excreta and food waste be removed from primary enclosures or from under primary enclosures at least daily and as often as necessary. This daily cleaning requirement would apply to all types of housing facilities and to primary enclosures with grill-type floors, and to the ground areas under raised runs with wire or slatted floors. Our experience indicates that daily cleaning is necessary to prevent the accumulation of feces and food waste and to reduce disease hazards, pests, insects, and odors. We are also proposing to require that when a primary enclosure is cleaned by steam or water, any dog or cat in the enclosure be removed during

the cleaning process, to prevent the animal from being involuntarily wetted or injured.

Sanitization of Primary Enclosures and Food and Water Receptacles

The provisions of proposed § 3.10(b) regarding sanitization of primary enclosures and food and water receptacles would be basically the same as those in § 3.7(b) of the current requirements, except that we would allow the option of sanitizing with live steam under pressure. Additionally, we would make minor editorial changes to the current regulations.

Housekeeping

In proposed § 3.10(c), we would revise and reword § 3.7(c) of the current regulations regarding housekeeping to clarify that paragraph's intent. The current regulations require that premises be kept free of trash accumulations and be kept clean enough and in good enough repair to protect the animals and facilitate the husbandry practices required by Subpart 3 of the regulations. We would retain the current requirements, but would add language to clarify that one of the aims of the housekeeping provisions is to keep premises rodent-free; additionally, we would specify what we would require as good housekeeping practices. We would specify that premises must be kept free of accumulations of trash, junk, waste products, and discarded matter such as wood, bricks, and abandoned cars. Weeds, grasses, and bushes would have to be controlled so as to facilitate cleaning and pest control, and to protect the dogs' and cats' health and well-being from hazards such as fox tails, burrs, sharp twigs, and fires.

Pest Control

The provisions of proposed § 3.10(d) regarding pest control would be basically the same as those in § 3.7(d) of the current requirements. We are proposing some minor revisions to simplify the language used. We are also proposing to clarify that a pest control program is necessary to promote the health and well-being of the dogs and cats at a facility and to reduce contamination by pests in animal areas.

Employees

Current § 3.8 requires that there be a sufficient number of employees to maintain the prescribed level of husbandry practices required by Subpart A and that husbandry practices be under the supervision of an animal caretaker with a background in animal husbandry or care. We are proposing minor revisions to this section in proposed § 3.11 to make clear that this requirement is imposed upon every person subject to the regulations and that the burden of verifying and ensuring that the supervisor and other employees are appropriately qualified is on the employer subject to the regulations. We are not proposing to prescribe a specific number of employees for each facility, because the number of employees needed will vary according to the size and configuration of the facility, and according to the number and type of animals housed there. We would require that a facility have enough employees to carry out proper feeding, cleaning, observation, and other generally accepted professional and husbandry practices.

Social Grouping

We are proposing to slightly revise current § 3.9 regarding social grouping of dogs and cats in order to reduce the stress suffered by certain dogs and cats. Under proposed § 3.12(d), we would allow dogs and cats to be maintained together in the same primary enclosure, or to be maintained in the same primary enclosure with other species of animals, if they are compatible. The present regulations require that dogs and cats be kept separate from each other, and from other animals, regardless of how well they get along together, or whether they are distressed by separation because they have been raised together and are compatible. If dogs and cats are not compatible with each other or with other animals, keeping them in the same primary enclosure would continue to be prohibited.

Transportation Standards

Consignments to Carriers and Intermediate Handlers

The current obligations imposed upon carriers and intermediate handlers (defined in Part 1 of the regulations) would be expanded to ensure the well-being of dogs and cats during transport in commerce. Certain prerequisites must be satisfied before carriers and intermediate handlers may accept dogs and cats for transport in commerce. Additionally, the carriers and intermediate handlers had certain duties to fulfill after the shipment has reached its destination. Various obligations are presently contained in current §§ 3.11 and 3.14. We are proposing to consolidate them in one section, proposed § 3.13, and to add some additional ones that are necessary for the dogs' and cats' welfare.

The reader should note that our proposed regulations do not specifically refer to operators of auction sales, unlike the current regulations. The definition of the term "dealer" was amended in 1976 to include any person who "negotiates the purchase or sale" of animals for research, teaching, exhibition, or use as a pet. Operators of auction sales are therefore dealers. However, we did not remove the reference to them in the 1977 amendments to the regulations. We are proposing to do so now, to clarify the regulations. Accordingly, all references to dealers in the regulations would include operators of auction sales.

We would remove from the regulations the requirements that certifications accompanying shipments of dogs and cats include an "assigned accreditation number" (as provided in current § 3.11(c)(4)), because the program under which accreditation numbers are assigned has not been implemented.

Proposed § 3.13(c) would require that written instructions concerning food and water requirements for each dog and cat in the shipment be securely attached to the outside of the primary enclosure before a carrier or intermediate handler can accept it for transport. This requirement is contained in current § 3.14(d). The instructions would have to be easily noticed and read. Current § 3.14 also requires that adult dogs and cats be given food at least once every 24 hours after acceptance for transportation, and water at least once every 12 hours after acceptance for transportation. It is conceivable under these regulations that a dog or cat could have been fed up to 24 hours before being consigned for transport in commerce and would then not be offered food for another 24-hour period. To avoid this occurrence, we are proposing to add a certification requirement to proposed § 3.13(d) that would require that a carrier or intermediate handler not accept a dog or cat for transport in commerce unless certification by the consignor accompanies the animal and specifies in writing the date and time each dog and cat was last provided food and water before acceptance for transport. Proposed § 3.16 would require that the time periods for feeding and watering the dogs after acceptance for transport begin with the time of the last feeding and watering before acceptance for transport. To avoid situations where the carrier or intermediate handler would have to provide food and water immediately after accepting the animals, we would require that the certification also state that the dogs and cats were provided water within the 4 hours before delivery to the carrier or

intermediate handler, and were provided food within 12 hours before delivery to the carrier or intermediate handler.

Carriers and intermediate handlers would not be allowed to accept dogs and cats for transport unless the certification described above is signed and dated by the consignor, and the time of the execution of the certification is included. This certification as well as others required in proposed § 3.13 would have to include the tag number or tattoo assigned to each dog and cat under § 2.50 of the regulations.

The certifications of the consignor regarding the acclimation of a dog or cat to lower temperatures than those prescribed in current §§ 3.16 and 3.17 of the regulations (included in proposed §§ 3.18 and 3.19) would be clarified. Proposed § 3.14(f) would clarify the provisions in § 3.11(c) to require that the temperatures to which a dog or cat is exposed must meet generally accepted temperature ranges for the age, condition, and breed of the animal, even if it is acclimated to temperatures lower than those prescribed in the regulations. A carrier or intermediate handler would not be permitted to expose a dog or cat to temperatures lower than those prescribed by the regulations, unless a veterinarian certifies that the animal is acclimated to such lower temperatures, and unless the veterinarian includes in the certification the minimum temperature to which the animal may be exposed.

Proposed § 3.13(g) would retain the provision in current § 3.11(d) that requires the carrier or intermediate handler to attempt to notify the consignee of the arrival of the animal upon arrival, and every 6 hours after arrival. Proposed § 3.13(g) would also include limitations on how long a dog or cat can be held at a terminal facility while waiting to be picked up by the consignee. The same time limitations are imposed under Part 2 of the regulations, § 2.80, "C.O.D. shipments" (*see* companion docket no. 88–014, published elsewhere in this issue of the **Federal Register**), so that the carrier or intermediate handler must attempt to notify the consignee for 24 hours after arrival, then must return the animal to the consignor or to whomever the consignor designates if the consignee cannot be notified. If the consignee is notified and does not take physical delivery of the dog or cat within 48 hours of notification, the carrier or intermediate handler must likewise return the animal to the consignor or to whomever the consignor designates. Proposed § 3.13(g) would also require that carriers and intermediate handlers continue to maintain dogs and cats in accordance with generally accepted professional and husbandry practices as long as the animals are in their custody and control and until the animals are delivered to the consignee or to the consignor or to whomever the consignor designates. We would require that the carrier or intermediate handler obligate the consignor to pay for expenses incurred by the carrier or intermediate handler in returning the animal to the consignor.

All of these certifications and notification requirements would help minimize and alleviate many of the stresses of travel for dogs and cats and accordingly are necessary for their general welfare and well-being.

Primary Enclosures Used to Transport Dogs and Cats

We are proposing to reformat current § 3.12, which concerns primary enclosures used to transport dogs and cats, and to move those provisions to proposed § 3.14. Additionally, we are proposing to revise the contents of several paragraphs in the section, and add requirements for surface transportation. When the transportation standards were rewritten in 1978 to incorporate the 1976 amendments to the Act concerning the commercial transportation of animals, the existing standards for surface transportation were inadvertently omitted. Since that time, the standards have pertained to the commercial transportation by common carrier and only a few subsections have pertained to surface transportation by private vehicle. This omission has caused numerous difficulties in the enforcement of standards regarding surface transportation of dogs and cats, and in the prosecution of persons who have improperly handled and transported dogs and cats by private surface vehicle. We are therefore proposing to reinstate the surface transportation standards that were inadvertently omitted in 1978.

We would require in § 3.14(a) that dogs and cats be shipped in primary enclosures. In addition to the requirements in current § 3.12(a) regarding construction of primary enclosures used for transportation, we are proposing to require in § 3.14(a) that the primary enclosure be constructed so that: (1) The animal being transported is at all times securely contained within the enclosure and cannot put any part of its body outside of the enclosure in a way that could injure the animal or people; (2) any material used in or on the enclosure is nontoxic to the animal; and (3) if a slatted or wire mesh floor is used in the enclosure, it be constructed so that the animal cannot put any part of its body through the spaces between the slats or through the holes in the mesh. Unless the dogs and cats are on raised floors made of wire or other nonsolid material, the primary enclosure would have to contain enough previously unused litter to absorb and cover excreta.

In addition to retaining the cleaning and sanitization requirements that currently appear in § 3.12(e), we would also require in proposed § 3.14(b) that if the dogs or cats being transported are in transit for more than 24 hours, either the enclosures be cleaned and the litter replaced, or other means, such as moving the animals to a different enclosure, be used to prevent the soiling of the dogs or cats by body wastes.

In proposed § 3.14(c), we set forth ventilation requirements more restrictive than those in the current regulations by removing two of the current options for primary enclosure configurations with regard to ventilation. The current regulations allow the primary enclosures to have ventilation openings on either two, three, or four sides. Studies made by the Civil Aeromedical Institute, Federal Aviation Administration, Oklahoma City, OK, indicate that maximized ventilation with regard to transportation crates is beneficial to the well-being of dogs, by allowing them to adjust better to the high temperatures and humidity encountered when shipped in warm weather. These studies also indicate that, within reason and for short periods of time, increased ventilation in transportation crates is not detrimental to dogs during cold weather. Therefore, we are proposing to require that there be ventilation openings on each of the four walls of primary enclosures used to transport dogs and cats, and that the ventilation openings total at least 8 percent of the total surface of each wall, with the total combined surface area of the ventilation openings comprising at least 14 percent of the total combined surface area of all the walls of the primary enclosure.

Section 3.12(h) of the current regulations requires that a primary enclosure that is permanently affixed to a primary conveyance so that the front opening of the enclosure is its only source of ventilation must face either the outside of the conveyance or an unobstructed aisle or passageway. Because primary enclosures that open directly to the outside of the conveyance may expose the animals in the enclosure to the elements, we are proposing in § 3.14(c)(3) to require that enclosures

with a front opening open only to an unobstructed aisle or passageway. We are also proposing in § 3.14(c)(3) to require that the ventilation openings of primary enclosures permanently affixed to a conveyance be covered with bars, mesh, or smooth expanded metal having air spaces. Under the current regulations, § 3.12(b) requires that live dogs or cats transported in the same primary enclosure be of the same species and be maintained in compatible groups. We are proposing to retain this wording in proposed § 3.14(d), with the added provision that dogs and cats that are private pets, are of comparable size, and are compatible, may be transported together in the same primary enclosure. Based on our observations of shipments of dogs and cats and on information received from pet owners and dealers, we have determined that shipping companion animals individually may cause them more stress than shipping them together.

We are also proposing in § 3.14(d) that: (1) Puppies or kittens 180 days of age of less may not be transported in the same primary enclosure with adult dogs or cats other than their dams; (2) dogs or cats that are aggressive or vicious must be transported individually in a primary enclosure; and (3) female dogs or cats in season (estrus) must not be transported in the same primary enclosure with any male dog or cat.

The requirement in § 3.12(c) that each dog or cat transported in a primary enclosure have sufficent space to turn about freely in a standing position, and to sit, and lie in a natural position would be retained and moved to proposed § 3.14(e)(1).

Transportation by Air

Because certain requirements for primary enclosures used in surface transportation were omitted from the 1978 revisions to the regulations, the provisions in current § 3.12(d) regarding the number of animals that may be transported in a primary enclosure are designed only for air transportation. We are therefore proposing to set forth the provisions of current § 3.12(d), with some amendments, in proposed § 3.14(f), titled "Transportation by air." We are proposing that a maximum of two live dogs or cats, 6 months of age or more, that are comparable in size, may be transported in the same primary enclosure when shipped by air. The present standard allows only one dog or cat, 6 months or more of age, to a container. Although the current regulations were establish to minimize stress on animals being shipped, we have determined from our observations at airports, and from information received from pet owners and dealers, that it is often more stressful for a dog or cat to travel alone than in an enclosure with a companion animal.

We are also proposing that a maximum of two live puppies, 8 weeks to 6 months of age, of comparable size, and weighing over 20 lb (9 kg) each may be transported in the same primary enclosure. Present standards allow only one such puppy per primary enclosure. The present standards also allow only two live puppies and kittens, 8 weeks to 6 months of age, but not weighing over 20 lb (9 kg) each, to be shipped in the same primary enclosure. We are proposing that it be permissible to transport a maximum of three such puppies or kittens in the same primary enclosure. As we noted above, we believe it is appropriate to allow an animal being shipped the opportunity for companionship, and the small size of the animals described by this provision would allow three animals to be shipped comfortably in standard air shipping enclosures. In proposed § 3.14(f)(4), we would retain the provision in current § 3.12(d) that weaned puppies or kittens less than 8 weeks old and of comparable size, or puppies or kittens that are less than 8 weeks old and are littermates accompanied by their dam, may be shipped in the same primary enclosure to research facilities. This provision is limited to research facilities by the Act.

Transportation by Surface Vehicle

We are proposing to add a new § 3.14(g) regarding transportation by surface vehicle. These provisions would reinstate primary enclosure requirements that were inadvertently omitted when the standards for the commercial transportation of dogs and cats were revised in 1978. We are proposing that a maximum of four dogs or cats may be transported in the same primary enclosure when shipped by surface vehicle, provided all other transportation requirements in proposed § 3.14 are complied with. We would allow shipment of more dogs and cats in surface vehicle enclosures than in air shipping enclosures for several reasons. First, standard enclosures for surface transportation are larger than than those customarily used for air transportation. Additionally, when animals are transported by surface vehicle, there is more opportunity for the driver or another person to check on the animals to ensure that their health is being maintained and that the animals are compatible.

Weaned live puppies or kittens less than 8 weeks of age, or puppies or kittens that are less than 8 weeks of age, are littermates, and are accompanied by their dam, would be permitted to be transported in the same primary enclosure when shipped to a research facility, including federal research facilities.

Documents Accompanying Animals

Proposed § 3.14(h) would require that shipping documents accompanying the shipments either be maintained by the operator of the conveyance or be securely attached in a readily accessible manner to the outside of the primary enclosures in a way that allows them to be detached for examination and securely reattached. Instructions for food and water and for administration of drugs, medication, and other special care would have to be attached to each primary enclosure in a manner that makes them easy to notice, to detach for examination, and to reattach securely.

Primary Conveyances

To protect the health of dogs and cats during transportation in commerce, the regulations in current §§ 3.16 and 3.17 prohibit animals in transporting devices or holding areas of terminal facilities from being subjected to temperatures above or below a specified range. Temperature is also of concern when animals are being transported in the cargo spaces of primary conveyances. Until 1978, requirements concerning allowable temperatures in primary conveyances were included in § 3.13 of the regulations. However, these requirements were inadvertently omitted from the regulations during the last major revision in 1978.

The intervening years have demonstrated the need to reinstated these requirements for two principal reasons: (1) The current requirements concerning temperatures in primary conveyances are inconsistent, because dogs and cats in transporting devices and in holding areas of terminal facilities must not be exposed to temperature outside a specified range, but dogs and cats in animal cargo spaces of primary conveyance—mainly cars and trucks—are not afforded the the same protection; and (2) as air freight rates have risen dramatically during this time, increasing numbers of animals are being shipped by surface transportation—some for very long distances—with no provision that the animals are not subjected to extremes of temperature.

Under the requirements for air transportation in proposed § 3.15(d), we would specify that during transportation, including time spent on the ground, live dogs and cats must be transported in cargo areas that are

heated or cooled as needed to maintain the required ambient temperature. The cargo areas would also have to be pressurized while the conveyance is in the air. In proposed § 3.15(e), we would require that during surface transportation, auxillary ventilation, such as fans, blowers or air conditioning, be used in animal cargo spaces containing live dogs or cats when the ambient temperature within the animal cargo space is 85 °F (29.5 °C) or higher. Additionally, the ambient temperature would not be permitted to exceed 95 °F (35 °C) at any time; nor to exceed 85 °F (29.5 °C) for a period of more than 4 hours; nor to fall below 45 °F (7.2 °C) for a period of more than 4 hours; nor to fall below 35 °F (1.7 °C) at any time. We are proposing to add requirements in proposed § 3.15(c) that a primary conveyance in a way that provides protection from the elements. Current § 3.13(f) requires that dogs and cats not be transported with any material, substance or device that may reasonably be expected to harm the animals. In proposed § 3.15 (h), we would clarify the intent of that requirement to indicate that the material, substance or device must not accompany the animals only the shipment is conducted "in a such a manner" that might be reasonably be expected to harm the dogs and cats.

Food and Water Requirements

Requirements regarding food and water for dogs and cats being transported, currently contained in § 3.14, would be set forth in proposed § 3.16. We would remove the provision concerning the minimum amount of water that must be offered to dogs or cats under 16 weeks of age. The current regulations require that these dogs and cats be offered at least 60 cc (approximately 2 oz) of potable water within a prescribed time. The minimum amount in the current regulations is so small that we believe the young dogs and cats would be better served by simply falling under the general requirements concerning the offering of potable water.

Current § 3.14(a) requires that dogs and cats be offered water within 12 hours after the start of transportation or acceptance for transportation. Current § 3.14(b) requires that puppies and kittens be provided food at least once every 12 hours, and dogs and cats over 16 weeks of age be provided food at least once every 24 hours. The current regulations specify that these time periods begin at the time the animals are accpeted for transport or the time transport begins, depending on who is carrying out the transport. This method of calculating when the time begins, however, could result in some dogs and cats not being provided water and food for unacceptably lengthy periods of time—in those cases where the animals were provided food and water the maximum time allowed before transport or acceptance for transport, and then not again until the maximum time allowed after transport or acceptance for transport. Therefore, we are proposing in §§ 3.16 (a) and (b) that the time periods for providing food and water to the animals *after* transport or acceptance for transport begin at the time the dog or cat was last provided food and water before initiation of transport or acceptance for transport.

In order to minimize the instances where carriers and intermediate handlers have to provide food and water to the animals immediately after accepting them for transport, consignors subject to the regulations would be required to certify that each dog or cat was provided water within 4 hours before delivery for transportation and that each dog or cat was provided food within 12 hours before delivery for transportation. The proposed regulations would require that the certification include the date and times the food and water was offered.

The provisions in current § 3.14(d), concerning a carrier or intermediate handler's responsibility regarding written feeding and watering instructions, would be set forth in proposed § 3.13(c). We are proposing to add the provision that food and water receptacles must be securely attached inside the primary enclosure and placed so that the receptacles can be filled from outside the enclosure without opening the door. We are proposing this provision based on information from carriers and intermediate handlers, which indicates that when a primary enclosure is opened to provide food or water to the animal inside, there is often a significant risk of the animal escaping from the enclosure.

§ 3.17 *Care in Transit.* The provisions regading care in transit in current § 3.15 would be set forth in proposed § 3.17. We are proposing some minor reformatting for readability, and three additions to the current provisions. The current regulations require that the driver of a surface vehicle check on the dogs or cats he or she is transporting. In proposed § 3.17(a), we would allow this observation to be conducted either by the operator of the conveyance or a person accompanying the operator, but would make it the responsibility of the regulated person transporting the dogs and cats to ensure that this observation is carried out. Additionally, in proposed § 3.17(a), we would use language that specifies that dogs and cats in obvious physical distress be given veterinary care at the closest available veterinary facility. We are proposing to make this change to clarify our intent as to the meaning of "as soon as possible" in the current regulations.

In proposed § 3.17(c), we would add an exception to the current regulations that prohibit transport in commerce of a dog or cat in physical distress, to allow transport for the purposes of obtaining veterinary care for the condition.

We are proposing to add a subsection § 3.17(e), that would specify that these transportation standards remain in effect and must be complied with until the animal reaches its final destination, or the consignee accepts delivery of the animal. We believe this provision is necessary to prevent any gap in care for the dog or cat and in responsibility for its care.

Terminal Facilities

Current § 3.16 imposes duties on carriers and intermediate handlers holding dogs or cats in animal holding areas of terminals to keep the animals away from inanimate cargo, to clean and sanitize the area, to have an effective pest control program, to provide ventilation, and to maintain the ambient temperature within certain prescribed limits. There is currently no similar obligation imposed on other persons who transport these animals. As a result, under the current regulations, animals could be held in animal holding areas under hazardous conditions.

We are proposing to move the provisions regarding terminal facilities to proposed § 3.18, and would require that the same duties be imposed on any person subject to the regulations who transports dogs or cats and who holds them in the animal holding areas. Because the animals require this minimum level of care no matter which regulated persons are moving them, it is illogical to place these duties only on carriers and intermediate handlers. Also, the length of time that dogs and cats can be maintained in terminal facilities upon arrival after transportation would be the same as that proposed in § 3.13(g).

Additionally, we are proposing to add in § 3.18(d) the provision that the ambient temperature in the animal holding area of terminal facilities may not fall below 35° F (1.7° C) at any time live dogs or cats are present. The proposed regulations would specify a procedure for measuring the ambient temperature. In cases where a terminal

facility contains more than one primary enclosure, it is possible that several temperature readings would have to be made to determine the ambient temperature at each primary enclosure. Also, proposed § 3.18(e) contains those provisions contained in current § 3.17 that require shelter from the elements for dogs and cats, because the current provisions apply to persons holding a dog or cat in an animal holding area of a terminal facility.

Handling

Current § 3.17 also imposes duties on carriers and intermediate handlers for proper handling and movement of dogs and cats. For reasons explained above under "Terminal facilities," proposed § 3.19 would also impose the same duties on any person subject to the regulations when handling a dog or cat at any time during the course of transportation in commerce, so that the animals' health, safety and well-being will be protected at all times during transport. This would include movement from an animal holding area of a terminal facility to a primary conveyance and from a primary conveyance to a terminal facility. This would also include movement of the dog or cat on a transporting device used to transfer the animal from a primary conveyance to an animal holding area and vice versa, movement from one primary conveyance to another, and movement from place to place within the terminal facility.

Proposed § 3.19(b) would require that care be exercised to avoid handling primary enclosures in such a way that dogs or cats in the primary enclosures are cuased physical or emotional distress. Because of problems and complaints concerning the handling of dog and cat shipments in baggage areas by airlines, we are proposing that primary enclosures containing dogs or cats must not be placed on unattended conveyor belts or on elevated conveyor ramps such as baggage claim conveyor belts and inclined conveyor ramps leading to baggage claim areas. We would allow primary enclosures to be placed on inclined conveyor ramps that are used to load and unload aircraft, if there is an attendant at each end of the conveyor belt.

Subparts B and C—Guinea Pigs, Hamsters, and Rabbits

Regulations on the humane handling, care, treatment, and transportation of guinea pigs, hamsters, and rabbits are contained in 9 CFR Part 3, Subpart B for guinea pigs and hamsters, and Subpart C for rabbits. These regulations include minimum standards for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperatures, veterinary care, and transportation.

We propose to amend these regulations by revising the space requirements for primary enclosures and by prescribing minimum and maximum temperatures for cargo spaces in primary conveyances. These proposed amendments are discussed in detail below.

Space Requirements for Guinea Pigs

Our current requirements concerning space in primary enclosures used to house guinea pigs (contained in § 3.28(b)(2)) are as follows:

Weight/stage of maturity	Floor area/ animal in [2]	Interior height in
Weaning to 350g	60	6.5
> 350g	90	6.5
Breeders	180	6.5

In May of 1987, the National Association for Biomedical Research (NABR) petitioned us to delete the requirement for additional space for breeder guinea pigs.

In its petition, the NABR cited a study performed at Charles River Laboratories, a major laboratory animal breeder located in Wilmington, Massachusetts. This study concerned the effect of cage size on reproductivity. As described in a report accompanying the petition, the study used three groups of 60 female guinea pigs each. One group was housed four guinea pigs to a cage of 720 square inches (180 square inches each), as prescribed by Animal and Plant Health Inspection Service (APHIS) regulations. Another group was housed six to a cage of 720 square inches (120 square inches each), and the third group was housed seven to a cage of 720 square inches (102.86 square inches each). The study showed no significant difference in the reproductive performance (gross litter averages, live births, average weaning litter sizes, and total number of pups weaned during the same timeframe) between the breeder guinea pigs housed according to APHIS regulations and the breeder guinea pigs housed in less space. These results indicate that breeder guinea pigs, including nursing females with litters, do not require floor space in excess of that required for nonbreeder guinea pigs.

The NABR also cited a study performed by the Department of Comparative Medicine of the Milton S. Hershey Medical Center at the Pennsylvania State University at Hershey, Pennsylvania. This study was conducted to determine the percent of available floor space used by groups of breeder guinea pigs. The study compared a group of four guinea pigs housed in a cage of 720 square inches (180 square inches each) with a group of seven guinea pigs housed in a cage the same size (102.86 square inches each). The study hypothesized that a decrease in floor area per animal would lead to increased use of the available floor area as animals tried to avoid stress associated with overcrowding. Conversely, the study also hypothesized that if herding or family grouping were important to the well-being of the animals, a decrease in floor space would not lead to an increased use of the available floor area. A computer-coupled video tracking system recorded the movement of the guinea pigs over 12-hour light and dark cycles. The study revealed that both groups of breeder guinea pigs used the periphery of the cage almost to the exclusion of the center floor space. These results provide a basis for changing our regulations concerning space requirements for breeder guinea pigs.

We have carefully reviewed and analysed the material submitted to us. We believe the data is sound and the petition has merit. Therefore, we propose to delete our requirement for additional space for breeder guinea pigs and to require the same minimum floor space for breeder guinea pigs, including nursing females with litters, as for nonbreeder guinea pigs.

We also propose to revise the space requirements in primary enclosures for nonbreeder guinea pigs weighing more than 350 grams.

Our current regulations require a minimum floor space of 90 square inches for nonbreeder guinea pigs weighing more than 350 grams. By comparison, the NIH Guide recommends 101 square inches for each guinea pig weighing over 350 grams, only slightly less than the 102.86 square inches provided each breeder guinea pigs housed in groups of seven in the Charles River and Hershey Medical Center studies.

Based on all the data available to us, we believe that more floor space for nonbreeder guinea pigs weighing over 350 grams would be beneficial, giving them more space for moving about. Therefore, we propose to increase, from 90 square inches to 101 square inches, the minimum floor space we require for guinea pigs weighing over 350 grams.

We also propose to require that primary enclosures used to house guinea pigs have a minimum interior height of 7 inches. This is an increase of ½ inch

over our current requirement of 6½ inches. We believe than an extra ½ inch in height would benefit guinea pigs by providing additional space for them to make normal postural adjustments.

Space Requirements for Hamsters

Our current requirements concerning space in primary enclosures used to house hamsters (contained in § 3.28(b)(3)) are as follows:

Age	Floor area/animal		Interior height		Maximum population per enclosure
	Dwarf in ²	Other in ²	Dwarf in ²	Other in ²	
Weaning to 5 wks	5.0	10.0	5.0	5.5	20
5 to 10 wks	7.5	12.5	5.0	5.5	16
> 10 wks	9.0	15.0	5.0	5.5	13

In addition, § 3.28(b)(3) requires that a nursing female hamster, together with her litter, be housed in a primary enclosure that contains no other hamsters and that provides at least 25 square inches of floor space for dwarf hamsters and at least 121 square inches of floor space for hamsters other than dwarf.

We believe that increasing both floor area and cage height would benefit hamsters by providing additional room for them to move about and make normal postural adjustments. We have carefully considered the space recommendations contained in the NIH Guide. We believe that they are an improvement over our current regulations. Therefore, we are proposing to adopt the same floor area and cage height requirements as are currently in the NIH Guide. Our requirements for females with litters would not be amended.

The NIH Guide contains the following minimum space recommendations for hamsters:

Weight g	Floor area/animal		Cage height	
	in ²	cm ²	in	cm
60	10	64.52	6	15.24
60 to 80	13	83.88	6	15.24
80 to 100	16	103.23	6	15.24
> 100	19	122.59	6	15.24

The NIH Guide notes that females with litters require additional space and refers readers to our regulations.

We also propose to delete our requirements concerning maximum population per enclosure because we believe that population is not a critical factor affecting the well-being of hamsters, as long as each hamster has at least the minimum amount of floor space that we have proposed.

Space Requirements for Rabbits

Our current requirements concerning space in primary enclosures used to house rabbits (contained in (§ 3.53(b)) are as follows:

Category	Weight/animal		Floor area/animal	
	lbs	(kgs)	in ²	(ft ²)
Groups	3–5	(1.4–2.7)	144	(1)
	6–8	(2.7–4.0)	288	(2)
	>9	(>4.0)	432	(3)
Individual adults	3–5	(1.4–2.7)	180	(1.25)
	6–8	(2.7–4.0)	360	(2.50)
	9–11	(4.0–5.4)	540	(3.75)
	>12	(>5.4)	720	(5.00)
Nursing females	3–5	(1.4–2.7)	576	(4.00)
	6–8	(2.7–4.0)	720	(5.00)
	9–11	(4.0–5.4)	864	(6.00)
	>12	(>5.4)	1080	(7.50)

We believe that rabbits, like guinea pigs and hamsters, would benefit from additional space. Based on all the data available to us, we believe that the current NIH guidelines would provide them with adequate space. These guidelines are different from our current regulations in two ways, which we have carefully considered and believe are improvements over our current regulations: (1) Space recommendations are for individual rabbits only; and (2) there is a minimum interior cage height of 14 inches. Under our proposal, this would mean that rabbits housed in groups would have to be provided the same amount of floor space per rabbit as those housed individually. It would also mean that rabbits would have adequate overhead space to accommodate normal physical posturing.

The NIH Guide contains the following minimum space recommendations for rabbits:

Weight kg	Floor area/animal		Cage height	
	ft²	m²	in	cm
2	1.5	0.14	14	35.56
2–4	3.0	0.28	14	35.56
4–5.4	4.0	0.37	14	35.56
>5.4	5.0	0.46	14	35.56

The NIH Guide notes that females with litters require additional space and refers readers to our regulations.

We also propose to revise our space requirements for females with litters to the following:

	Weight of female rabbit		Minimum area/female & litters [1]		Minimum interior hgt	
	lbs	kgs	ft²	m²	in	cm
Females with litters	4.4	2	4.0	0.37	14	35.56
	4.4–8.8	2–4	5.0	0.46	14	35.56
	8.8–11.9	4–5.4	6.0	0.56	14	35.56
	>11.9	>5.4	7.5	0.70	14	35.56

[1] The minimum floor spaces indicated in the table above are for the nursing female, together with her litter.

The proposed minimum space requirements for females with litters are roughly the same as the current requirements for nursing females. We are proposing new weight categories and a new term for nursing females to make the format of the proposed space requirements for females with litters parallel the format of the proposed space requirements for other rabbits.

Ambient Temperature Requirements in Primary Conveyances

To protect the health of guinea pigs, hamsters, and rabbits during transportation in commerce, the regulations in 9 CFR in Part 3, §§ 3.40, 3.41, 3.65, and 3.66, prohibit animals in transporting devices or holding areas of terminal facilities from being subjected to temperatures above or below a specified range.

Temperature is also of concern when animals are being transported in the cargo spaces of primary conveyances. Until 1977, requirements concerning allowable ambient temperatures in primary conveyances were part of the regulations in 9 CFR Part 3, §§ 3.37 and 3.62. However, these requirements were inadvertently omitted from the regulations during the last major revision in 1977.

The intervening years have demonstrated the need to re-adopt these requirements for two principal rseasons: (1) The current requirements concerning ambient temperatures are inconsistent, because guineas pigs, hamsters, and rabbits in transporting devices and in holding areas of terminal facilities may not be exposed to temperatures outside a specified range, but guinea pigs, hamsters, and rabbits in animal cargo spaces of primary conveyances—mainly cars and trucks—are not afforded the same protection; and (2) as air freight rates have risen dramatically during this time, increasing numbers of animals are being shipped by surface transportation—some for very long distances—with no provision to ensure that the animals are not subjected to extremes of temperature.

We therefore propose to reinstate requirements concerning ambient temperatures in primary conveyances. The proposed requirements, which would be applicable to all types of primary conveyances (motor vehicle, air, rail, and marine), would require animal cargo spaces in primary conveyances transporting live animals to be mechanically sound and to provide fresh air by means of windows, doors, vents, or air conditioning so as to minimize drafts, odors, and moisture condensation. We also propose to require that auxiliary ventilation be used in any animal cargo space containing live guinea pigs, hamsters, or rabbits if the ambient temperature is 75° F (23.9° C) or higher. Furthermore, we propose to require that the ambient temperature in the animal cargo space be maintained at or below 85° F (29.5° C) but no lower than 45° F (7.2° C), except that temperatures below 45° F (7.2° C) would be allowed for hamsters and rabbits if the animals are accompanied by a certificate of acclimation to lower temperatures. Requirements concerning the certificate of acclimation are contained in § 3.35 of the regulations for hamsters and in § 3.60 of the regulations for rabbits. We do not propose to allow guinea pigs to be transported in cargo spaces where the ambient temperature falls below 45° F (7.2° C) because guinea pigs cannot tolerate such low temperatures.

These proposed requirements concerning fresh air and auxiliary ventilation are necessary to ensure that the animals have adequate ventilation. The maximum and minimum ambient temperatures would help ensure that the animals are not subjected to extremes of temperature during transportation in commerce. We recognize, however, that some hamsters and rabbits may be comfortable at temperatures below the lower limits proposed; the provisions concering the certificate of acclimation would allow them to be transported at temperatures below 45° F (7.2° C).

Miscellaneous

We propose to revise §§ 3.40, 3.41, and 3.66 of the regulations, which contain transportation requirements, to clarify that responsibility for meeting these requirements rests with any person who is subject to the Animal Welfare regulations and who transports live guinea pigs, hamsters, or rabbits. Currently, the regulations place this responsibility only with carriers and intermediate handlers. However, other persons, including dealers, exhibitors, and research facilities, including federal research facilities, hold animals in terminal facilities and move animals in transporting devices, and the same temperature restrictions are necessary for the well-being of the animals.

We propose to revise §§ 3.36 and 3.61 of the regulations, which contain requirements for primary enclosures used to transport live guinea pigs, hamsters, and rabbits, to clarify that the responsibility for meeting these requirements rests with any person who

is subject to the Animal Welfare regulations and who offers a live guinea pig, hamster, or rabbit for transportation in commerce.

Subpart D—Nonhuman Primates

Regulations on the humane handling, care, treatment, and transportation of nonhuman primates are contained in 9 CFR Part 3, Subpart D. These regulations include minimum standards for handling, housing, social grouping and separation of species, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperature, veterinary care, and transportation.

We are proposing to revise and rewrite the current regulations based on our experience administering the Act and them. We are also proposing to amend our regulations to add requirements for a physical environment adequate to promote the psychological well-being of nonhuman primates. This is specifically required by the 1985 amendments to section 13 of the Act. (See § 1752, 99 Stat. 1645, Pub. L. 99-198, amending 7 U.S.C. 2143.) We discuss each topic covered in our proposed regulations below.

In preparing to revise and amend Subpart D, we engaged in extensive study of the environmental needs of nonhuman primates that must be met to promote their psychological well-being. We actively sought input from various professional communities that are subject to the regulations. We formed a committee to study the psychological needs of nonhuman primates maintained by the research community and to make specific recommendations to us concerning the various issues presented by the 1985 amendments to the Act. This committee was comprised of APHIS representatives and ten members of the scientific research community. The members were experts recommended by the National Institutes of Health and were appointed by APHIS to formulate recommendations for means of providing an environment to promote the psychological well-being of nonhuman primates. Observers from NIH were also present during committee deliberations, although they were not members of the committee.

We also sought and obtained input from organizations, such as the National Association for Biomedical Research, which represent facilities utilizing nonhuman primates in their research.

We invited animal exhibitors to participate in the development of regulations to promote the psychological well-being of nonhuman primates. The American Association of Zoological Parks and Aquariums, a nonprofit, tax-exempt organization dedicated to the advancement of zoological parks and aquariums for conservation, education, scientific studies and recreation, formed a Primate Study Committee to develop materials concerning space requirements and the various environmental enrichments required by different species of nonhuman primates, based upon their social behavior and species-typical activity, in order to promote their psychological well-being.

The results of these efforts are explained in greater detail below in our discussion of proposed minimum space and environmental requirements.

The regulations we are proposing in this revision of Subpart D are minimum standards to be applied to all species of nonhuman primates. We are continuing to include current footnote 1 of Subpart D in this proposal, although it is revised to reflect the need to promote the psychological well-being of nonhuman primates. Rather than stating that "discretion" must be used due to the variation in species, we are proposing to require that these minimum standards be applied in a manner that is considered appropriate for the relevant species in accordance with customary and generally accepted professional and husbandry practices.

The Act applies to all nonhuman primates, whether living or dead. The standards we are proposing are principally applicable to live nonhuman primates. As stated in proposed footnote 1, the proposed regulations apply only to live nonhuman primates, unless stated otherwise.

Housing Facilities and Operating Standards

Current sections 3.75 through 3.77 provide requirements for facilities used to house nonhuman primates. Current § 3.75, "Facilities, general," contains regulations pertaining to housing facilities of any kind. It is followed by current § 3.76, "Facilities, indoor," and § 3.77, "Facilities, outdoor." We are proposing to amend these sections to provide for an environment that better promotes the psychological well-being of nonhuman primates. We are also proposing to add sections that provide regulations specifically governing two other types of housing facilities used to house nonhuman primates, sheltered housing facilities and mobile or traveling housing facilities. The term "sheltered housing facility" is defined in Part 1 (*see companion docket no. 88-013, published elsewhere in this issue of the* **Federal Register**) as "a housing facility which provides the animals with shelter; protection from the elements; and protection from temperature extremes at all times. A sheltered housing facility may consist of runs or pens totally enclosed in a barn or building, or of connecting inside/outside runs or pens with the inside pens in a totally enclosed building." The term "mobile or traveling housing facility", also defined in Part 1, means "a transporting vehicle such as a truck, trailer, or railway car, used to house animals while traveling for exhibition or public education purposes."

Some of the requirements we are proposing for housing facilities are applicable to housing facilities of any kind. As in the current regulations, these standards of general applicability would be included in one section, proposed § 3.75, which would also include many of the provisions in current § 3.75. Additionally, we are proposing amendments to the current regulations that are specific to particular types of housing facilities, and are including those provisions in separate sections of the proposed regulations. In some cases, where the current regulations would be unchanged in substance, we have made wording changes to clarify the intent of the regulations.

Housing facilities, general

Because nonhuman primates vary widely in size, weight, and range of activity, the design, composition and structural strength required of housing facilities varies as well. We are proposing to require in proposed § 3.75(a) that the design, composition, and structural strength of a housing facility be appropriate for the particular species housed in it. For example, the actual structural requirements for a housing facility would differ depending upon whether it is used to house marmosets, a small nonhuman primate species, or great apes, a typically large species weighing more than 88 lbs. (40 kg.).

In proposed § 3.75(b), we are proposing to add the requirement that a dealer's or exhibitor's housing facilities be physically separated from any other business. When a housing facility is located on the same premises as any other business there is likely to be increased traffic and activity which is known to be distressful to nonhuman primates. Also when more than one dealer maintains facilities on the premises, it can be difficult to determine which dealer is responsible for which animals and for the conditions of the facility. This has made inspection and enforcement of the regulations difficult. To avoid these difficulties we are proposing to require that housing facilities, other than those maintained by research facilities and federal

research facilities, be physically separated from other businesses. This can be done by using a security fence or by conducting each business in a separate building. The means of separation used would have to be constructed so that it prevents unauthorized humans, and animals the size of dogs, skunks, and raccoons, from going through it or under it. For example, if a security fence is used, it would have to be at least 6-feet high and constructed in a manner that restricts any unauthorized entry. We are not imposing this requirement upon research facilities because they are often part of a larger sponsoring establishment, such as a university or pharmaceutical company, and responsibility for animal and site conditions rests with that establishment. Therefore, we have not encountered the enforcement difficulties noted above with research facilities.

We are also proposing in subsection (b) that housing facilities and areas used for storing animal food and bedding be kept free of any accumulation of trash, weeds, and discarded material in order to prevent unsanitary conditions, diseases, pests, and odors. The need for orderliness applies particularly to animal areas inside of housing facilities, and we are proposing that they must be kept free of clutter, including equipment, furniture, or stored material, and materials not necessary for proper husbandry practices.

In proposed § 3.75(c) we are proposing to include requirements concerning housing facility surfaces that are common to all types of facilities. The current regulations require that interior surfaces of indoor housing facilities be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized. They do not specify frequency of sanitization. They also do not provide any requirements for building surfaces used in outdoor housing facilities.

Under our proposal, any surfaces that come in contact with nonhuman primates must be maintained regularly so that they are kept in good condition. Interior surfaces and furniture-type fixtures or objects within the facility, such as perches, swings, and dens, must be made so that they can be readily cleaned and sanitized, or removed or replaced when worn or soiled. We are proposing to add this requirement because we would no longer require impervious surfaces under our proposal in an effort to encourage provision of more natural environments for the animals. Because porous surfaces may not be adequately sanitized, we are requiring instead that they be removed or replaced when worn or soiled. This requirement appears in proposed § 3.75(c)(2). Otherwise, the manner of construction and the materials used must allow for cleaning and sanitization.

Proposed § 3.75(c)(1) would require that surfaces that come in contact with nonhuman primates be free of jagged edges or sharp points that could injure the animals, as well as rust that prevents the required cleaning and sanitization or affects the structural integrity of the surfaces. Because we recognize that as long as water is used to clean animal areas metal parts will rust, we would allow some rust on metal areas. as long as it does not reduce structural strength or interfere with proper cleaning and sanitization because that could present hazards to the animals.

Proposed § 3.75(c)(3) would require that hard surfaces that come in contact with nonhuman primates be cleaned daily and sanitized at least once every two weeks and as often as necessary to prevent any accumulation of excreta or disease hazards, in accordance with generally accepted husbandry practices, unless the nonhuman primates engage in scent marking. Scent marking is an inborn method used by certain species of nonhuman primates in nature (such as species of prosimians, marmosets, tamarins, and callimico) to establish their territory and for identification by other members of the species. Animals can detect that another member of the species has occupied a site by the scent left behind and can locate companions in this manner. It is distressful for these primates to have their scent marks eliminated since they lose their territorial claims and their frame of reference. We are therefore proposing that hard surfaces that come in contact with nonhuman primates that scent mark be spot cleaned daily and that they be sanitized at regular intervals that would be determined in accordance with generally accepted professional and husbandry practices. We invite comments on the length of intervals that should be allowed to pass between regular cleanings for those species engaging in scent marking.

We are proposing to remove the requirement that housing facilities have impervious surfaces because many can simulate more natural environments by providing dirt floors and planted areas that are beneficial to the nonhuman primates' psychological well-being. Proposed § 3.75(c)(3) would provide that outdoor floors could be made of dirt, sand, gravel, grass, or other similar material that can be readily cleaned and is removable.

Proposed § 3.84(b)(3) provides various methods of sanitizing primary enclosures. Because these methods are effective in general for sanitization of hard surfaces that nonhuman primates come in contact with, except for dirt floors and planted areas, any of them could be used for the sanitization required by proposed § 3.75(c)(3). The method of sanitization would be determined by the housing facility operator. Planted enclosures and floors made of dirt, sand, gravel, grass, or other similar material would have to be raked and spot cleaned daily, since sanitization is not practicable. Contaminated flooring material would have to be removed if raking and spot cleaning does not eliminate odors, diseases, insects, pests, or vermin infestation. The material could then be replaced or a different material could be used.

In the current regulations, § 3.75(b) provides requirements for water and electric power. It specifies that reliable and adequate water and electric power must be made available "if required to comply with other provisions of this subpart." In this proposed rule, provisions concerning water and electric power are set forth in § 3.75(d). We are proposing there to eliminate the qualifying statement cited above, and to *require* reliable electric power that is adequate for heating, cooling, ventilation, lighting, and other husbandry requirements, and mechanically pressurized potable running water for the nonhuman primates' drinking needs and adequate for cleaning and for carrying out other husbandry requirements. Based upon our inspections of dealer, exhibitor, and research facilities, we believe that nonhuman primate facilities subject to the Animal Welfare regulations cannot be properly cleaned and maintained without electric power and running potable water under pressure.

We are proposing in § 3.75(e) to expand the regulations in current § 3.75(c) concerning proper storage of food and bedding supplies. We would retain the requirements that food and bedding be stored so as to protect them from vermin infestation or contamination, and that perishable food be refrigerated. We are proposing requirements to ensure further the quality of the physical environment surrounding nonhuman primates. We are proposing to add a requirement that food and bedding be stored in leakproof containers to protect the supplies from spoilage, contamination, and vermin infestation, and that open food and bedding supplies be kept in leakproof

containers with tightly fitting lids to prevent spoilage and contamination. Proposed § 3.75(e) would require that substances that would be toxic to nonhuman primates be stored away from animal areas and food storage and preparation areas. Only the food and bedding in use could be kept in animal areas and we would require that when they are not in use they must be properly stored. In addition, all food would have to be stored so as to prevent contamination or deterioration of its nutritive value. The supplies would have to be stored off the floor and away from the walls, to allow cleaning around and underneath them.

The proposed regulations would continue to require that housing facilities provide for removal and disposal of animal and food wastes, bedding, dead animals, and debris, as provided in current § 3.75(d). We are proposing to clarify this requirement so that it clearly applies to all fluid wastes and to include a requirement that arrangements must be made for prompt daily removal and disposal of wastes. Removal and disposal must be done more than once each day if necessary to avoid problems with odors, pests, insects, and diseases. The proposed regulations would also require that trash containers be leakproof and tightly closed when not in use, and that all forms of animal waste, including dead animals, be kept out of food and animal areas.

Requirements for drainage systems are currently provided in §§ 3.76(e) and 3.77(d) for indoor and outdoor facilities, respectively. Because all types of animal housing facilities, including sheltered housing facilities and mobile or traveling housing facilities, require a proper disposal facility and drainage system, we are proposing to consolidate all drainage and waste disposal requirements in proposed § 3.75(f). The requirements for drainage systems would be expanded to provide that in all types of housing facilities whether open or closed drains, waste sump ponds, or settlement ponds are used they must be properly constructed, installed, and maintained, and they must minimize vermin and pest infestation, insects, odors, and disease hazards. As part of this safeguard, we would require that waste sump ponds and settlement ponds be located an adequate distance from the animal area of the housing facility to prevent problems with vermin, pests, odors, insects, and disease hazards. Drainage systems must also rapidly eliminate animal wastes and water so that the animals can stay dry. This is necessary because it is known to be distressful to nonhuman primates to be involuntarily wetted.

The requirement contained in current § 3.75(e) that washing facilities be available to animal caretakers for their cleanliness would be retained and would appear in proposed § 3.75(g).

Requirements for different types of housing facilities

The current regulations specify two kinds of housing facilities, indoor and outdoor. These terms are defined in Part 1 of the regulations. (*See* companion docket no. 88–013, published elsewhere in this issue of the **Federal Register**.) An indoor housing facility is defined as "any structure or building with environmental controls housing or intended to house animals" that is fully enclosed and has a continuous connection between the floor, ground, and ceiling, is capable of being temperature and humidity controlled, and has at least one door for entry and exit. An outdoor housing facility is defined as "any structure, building, land, or premise, housing or intended to house animals, and which does not meet the defintion of an indoor housing facility or a sheltered housing facility and in which temperatures cannot be controlled within set limits. We are proposing to add two additional sections containing requirements for sheltered housing facilities and mobile or traveling housing facilities, previously defined in this document.

Requirements for enclosed or partially enclosed housing facilities

Three of the four types of housing facilities that may be used to house nonhuman primates are either enclosed or partially enclosed. They are indoor housing facilities, mobile or traveling housing facilities, and the sheltered portion of sheltered housing facilities. We are proposing to require that all of these enclosed types of housing facilities be required to provide heating, cooling, and ventilation, and to maintain temperatures within the temperature limits provided in current paragraphs (a) and (b) of § 3.76 "Facilities, indoor" as follows:

1. Temperature requirements

Under our proposal, there must be sufficient heat provided to protect nonhuman primates from cold temperatures. The ambient temperature (defined in Part 1 of the regulations as the temperature surrounding the animal) must not fall below 50 °F (10 °C). We would require cooling to protect nonhuman primates from high temperatures. The ambient temperature must not rise above 85 °F (29.5 °C), except that for mobile or traveling housing facilities only, the upper temperature limit is 95 °F (35 °C) when nonhuman primates are present, however auxiliary ventilation such as fans or air conditioning must be provided if the temperature is 85 °F (29.5 °C) or higher. Because the various species of nonhuman primates have different optimal ambient temperatures and different tolerances for higher and lower temperatures, we are proposing to require that the actual ambient temperature maintained be at a level that ensures the health and well-being of the species housed, in accordance with generally accepted professional and husbandry practices.

2. Ventilation

The current requirement in § 3.76(b) for ventilation of indoor housing facilities would be applicable to the three types of enclosed housing facilities to provide for the health, comfort, and well-being of nonhuman primates. For sheltered housing facilities the requirement would only apply to the sheltered portion of the facility since the outdoor portion could not be humidity controlled. We are proposing to add that ventilation must also be provided to minimize ammonia levels in these housing facilities and that mobile or traveling housing facilities must be ventilated to minimize exhaust fumes, to protect the well-being of the nonhuman primates.

3. Relative humidity level

Except in mobile or traveling housing facilities, we would also require that the relative humidity in enclosed facilities be maintained between 30 and 70 percent. The actual relative humdity maintained would depend upon the species housed and must be maintained at a level that ensures the health and well-being of the species housed, in accordance with generally accepted professional and husbandry practices. For example, certain species of nonhuman primates are known to be less tolerant of a wide range of humidity levels and therefore should be maintained at more specific humidity levels. The NIH Guide provides precise humdity levels for certain species. Individuals subject to our regulations can refer to the NIH Guide for these animals because use of the Guide will maintain actual humidity levels within the requirements of these regulations and conforms with generally accepted professional and husbandry practices.

We are not proposing to require that a precise range of humidity levels be maintained in mobile or traveling

housing facilities since they travel into all parts of the United States which have varying levels of humidity. Typically, the species of nonhuman primates that travel in these facilities are chimpanzees used in circuses and trained animal acts. Chimpanzees can tolerate a wider range of relative humidity levels than most species of nonhuman primates and would not be exposed to an undue health hazard if there is no range of humidity levels specified in the regulations. However, we would require that the relative humidity level be maintained at a level that ensures the health and the well-being of the species housed, in accordance with generally accepted professional and husbandry practices. Operators of mobile or traveling housing facilities as well as all other housing facility operators would still be subject to the general requirement contained in footnote 1 which provides that these regulations must be applied in accordance with customary and generally accepted professional and husbandry practices considered appropriate for each species and accordingly could not expose nonhuman primates to relative humidity levels that are considered hazardous to that species' physical well-being without violating the regulations.

4. Lighting

The proposed regulations would continue the requirement presently imposed upon indoor facilities in current § 3.76(c) to provide adequate light to premit routine inspection and cleaning of the housing facility, and observation of nonhuman primates. This requirement would apply to the three types of enclosed housing facilities included in the proposed regulations. We are proposing in proposed §§ 3.76(c), 3.77(c), and 3.79(d) to require a daily lighting cycle of at least 8 consecutive hours of light and at least 8 consecutive hours of darkness each day in order to maintain a normal lighting cycle for the nonhuman primates' well-being. A diurnal lighting cycle is known to be necessary for nonhuman primates to maintain normal breeding practices and to promote their psychological well-being. We would continue to allow artificial light to be used, but the proposed regulations would specify that it must provide full-spectrum illumination. Safeguards against exposing nonhuman primates to excessive light would be retained and would apply to all enclosed housing facilities

Requirements for outdoor or partially outdoor housing facilities

1. Shelter from the elements.

Outdoor housing facilities cannot be temperature controlled. Our proposal would allow only those nonhuman primates that are acclimated to the prevailing seasonal temperature and that can tolerate without stress or discomfort the range of temperatures, humidity, and climactic conditions known to occur at the facility at the time of year they are housed there to be housed in outdoor facilities, in order to protect their physical welfare.

As in current § 3.77(a)–(c) outdoor housing facilities must provide shelter from the elements and protection from various weather conditions, such as sun, wind, rain, cold air, and snow. For example, nonhuman primates must be provided with shade from the sun and protection from precipitation so that they remain dry. This requirement appears in proposed § 3.78(b). We would require that the shelter provided be maintained in good repair, and that it be constructed in a manner and made of material that can be radily cleaned and sanitized in accordance with proposed § 3.75(c). The shelter provided in an outdoor or sheltered housing facility would be required to provide heat to prevent the temperature from falling below 50 °F (10 °C).

The requirement to provide protection from the elements would also be applicable to sheltered housing facilities. We would require that nonhuman primates be provided shelter from the elements at all times. Accordingly, unless the nonhuman primates have continual ready access to the sheltered portion of the facility, some additional form of shelter must be provided that satisfies the requirements contained in paragraphs (a) through (e) of proposed § 3.77.

Proposed §§ 3.77(e) and 3.78(c) would require that the shelters in both sheltered and outdoor housing facilities be large enough to provide protection comfortably to all the nonhuman primate housed in the facility at the same time. Sheltered housing facilities and outdoor housing facilities would be required to have multiple shelters if there are aggressive or dominant animals present that might deter other nonhuman primates from utilizing the shelters when they so desire. We considered multiple shelters necessary under these circumstances in order to prevent the destress that would result if a nonhuman primates was prevented from occupying a shelter because it was intimidated.

2. Perimeter fence.

We are proposing additional requirements for housing facilities having outdoor areas, in order to protect the safety of nonhuman primates and to provide for their well-being. In proposed §§ 3.77(f) and 3.78(d), we would require that unless a natural barrier exists that would restrict the animals to the housing facility and prevent unauthorized humans and animals from having contact with the nonhuman primates, a perimeter fence at least 6 feet in height be placed around the outdoor areas of sheltered housing facilities and outdoor housing facilities, and that it be placed at least 3 feet from the outside wall of the primary enclosure. In certain settings a perimeter fence is not needed because the animals are protected by natural barriers, such as moats or swamps surrounding the facility. The exception for natural boundaries would be subject to the Administrator's approval. The perimeter fence could be slatted, latticed or of other similar design, as long as it is designed and constructed in a manner that restricts unauthorized humans and animals from entering or have contact with the nonhuman primates, including animals capable of digging underneath it, and that prevents small animals the size of dogs, raccoons, and skunks from entering through it. We would require that it be placed at least 3 feet from the outside wall of the primary enclosure because this is considered to be a sufficient safety zone between the nonhuman primates and the public and would allow sufficient room to use cleaning equipment necessary for cleaning the waste and refuse that nonhuman primates throw into it. The fence would not be required if the outside walls of the primary enclosure are high enough and built in a manner that prevents contact with or entry by other animals. To avoid the need for a perimeter fence we would require that the outside walls of the primary enclosure be made of a heavy duty material such as concrete, wood, metal, plastic, or glass, that prevents unauthorized entry by and contact with humans and animals.

Additional safety requirement

We are also proposing to add a requirement for facilities that are at least partially outdoors and are accessible to the public in order to protect nonhuman primates from the public and to protect the public from nonhuman primates. Public barriers would be required for sheltered housing facilities under proposed § 3.77(g),

outdoor housing facilities under proposed § 3.78(e), and for mobile or traveling housing facilities under proposed § 3.79(e). The proposed regulations would require barriers preventing unauthorized physical contact between the public and nonhuman primates for fixed public exhibits and traveling animal exhibits, at any time the public is present, both to protect the public and the nonhuman primates. We are also proposing to require that nonhuman primates used in trained animal acts or uncaged public exhibits be under the control and supervision of an experienced handler or trainer whenever the public is present. The proposed regulations would permit trained nonhuman primates used in animal acts and uncaged public exhibits to have physical contact with the public, as allowed under § 2.131, but only if the nonhuman primates are under the direct control and supervision of an experienced handler or trainer at all times during the contact, in order to prevent injury to both the nonhuman primates and the public.

Primary enclosures

We are proposing to revise completely current § 3.78, "Primary enclosures." We are doing so in accordance with the 1985 amendments to the Act. Under the amendments, the Secretary of Agriculture is directed to "promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors." The standards must include minimum requirements "for a physical environment adequate to promote the psychological well-being of primates." (7 U.S.C. § 2143(a)(2)(B)) Included among the primary enclosures subject to the regulations would be those used by circuses, carnivals, traveling zoos, educational exhibits, and other traveling animal acts and shows. As explained in greater detail below, we are proposing different minimum space and environment requirements for research facilities, dealers, exhibitors, and traveling or mobile animal act exhibitors, in order to promote the psychological well-being of nonhuman primates and to provide for the primates' minimum needs. All primary enclosures would be required to meet the proposed minimum requirements. We consider the proposed requirements to be the minimum necessary for nonhuman primates' health, safety, and psychological well-being.

Our proposal is in contrast to current § 3.78, which provides general requirements for construction and maintenance of primary enclosures and uniform space requirements for every nonhuman primate housed in a primary enclosure.

We are also proposing to add a subsection on social grouping of nonhuman primates within primary enclosures.

General requirements

Primary enclosures are defined in Part 1 of the regulations as "any structure or device used to restrict an animal to a limited amount of space, such as a room, pen, run, cage, compartment, pool, hutch, or tether." Proposed § 3.80(a) would continue to require that primary enclosures be structurally sound and maintained in good repair to protect the animals from injury, to contain them, and to keep predators out, that they enable the animals to remain dry and clean, that they provide the animals with convenient access to clean food and water, that their floors be constructed in a manner that protects the animals from injury, and that they provide sufficient space for the nonhuman primates to make normal postural adjustments with freedom of movement.

We are also proposing in proposed § 3.80(a) to require specifically that the primary enclosures have no sharp points or edges that could injure the animals, that they keep unauthorized people and predators from entering the enclosure or having physical contact with nonhuman primates, that they provide shelter and protection from extreme temperature and weather conditions that can be dangerous to the animals' health and welfare, that they provide sufficient shade to protect all the animals contained in the enclosure at one time, and that they enable all surfaces to be readily cleaned and sanitized or replaced if worn or soiled.

These additional requirements are intended to provide more specific minimum criteria that must be satisfied by regulated persons maintaining nonhuman primates in order to provide for the welfare of the animals.

Social grouping

We are proposing to include a new subsection of proposed § 3.80 "Primary enclosures" to emphasize that nonhuman primates must be grouped in a primary enclosure with compatible members of their species or with other nonhuman primate species, either in pairs, family groups, or other compatible social groupings, whenever possible and consistent with providing for the nonhuman primates' health, safety, and well-being, unless social grouping is prohibited by an animal care and use procedure and approved by the facility's Committee. Compatibility would be based upon generally accepted professional practices and upon observation of the nonhuman primates to determine that they are in fact compatible. We are proposing this requirement based upon scientific evidence and our experience, both of which indicate that nonhuman primates are social beings in nature and require contact with other nonhuman primates for their psychological well-being. The expert committee convened by APHIS also recommended social grouping to promote the psychological well-being of nonhuman primates. Social deprivation is regarded by the scientific community as psychologically debilitating to social animals. Where social grouping is not possible or is determined by the attending veterinarian to be contrary to providing for the nonhuman primates' health, safety, and well-being as explained below, or is prohibited by an animal care and use procedure approved by the research facility's Committee in accordance with Part 2 of the regulations, we are proposing to require that nonhuman primates be at least able to see and hear other nonhuman primates, unless this is also prohibited by an animal care and use procedure approved by the research facility's Committee. In this case, the isolated individually housed nonhuman primates would be required to have positive physical contact or other interaction with their keeper or with another familiar and knowledgeable person for at least one hour each day. We invite comments addressing the different measures that may be taken to satisfy the requirement to provide positive physical contact or other interaction to individually housed nonhuman primates.

Space and physical environment

As stated above, we are completely revising the minimum space requirements for nonhuman primates set forth in current paragraphs (1) and (2) of § 3.78(b). The current requirements specify that primary enclosures be "constructed and maintained so as to provide sufficient space to allow each nonhuman primate to make normal postural adjustments with adequate freedom of movement" and provide a minimum floor space equal to an area of at least three times the area occupied by each animal when standing on four feet, regardless of the size or condition of the animal. We are also proposing to add requirements for enhancing the environment of the primary enclosures used for maintaining nonhuman

primates, in accordance with the 1985 amendments to the Act.

In preparing our proposal of minimum requirements for a physical environment adequate to promote the psychological well-being of nonhuman primates, we utilized the Agency's expertise and experience in regulating the humane handling, care, and treatment of nonhuman primates. Because this is the first occasion the Agency has been charged with responsibility for regulations to promote the psychological well-being of nonhuman primates, we considered it important and instructive to consult with experts and representatives of regulated industries. We requested their advice on the minimum space and other environmental requirements they considered necessary to meet the psychological needs of nonhuman primates.

As stated previously in this Supplementary Information, the National Institutes of Health (NIH), Public Health Service recommended experts to advise us regarding minimum standards for promoting the psychological well-being of nonhuman primates. A group of 10 nonhuman primate experts was selected and was asked to formulate a recommendation for these minimum standards. We also requested the American Association of Zoological Parks and Aquariums (AAZPA) to recommend minimum requirements. Both groups presented us with a comprehensive report consisting of their recommendations for appropriate space requirements, environmental enhancements, social grouping and interaction, and other minimum standards they considered necessary to promote the psychological well-being of nonhuman primates. The consensus of opinion was that nonhuman primates need physical and mental stimulation for their psychological well-being, to enhance their developmental growth, and to make them better socially adjusted. The reports indicated that the need for stimulation could be met by allowing them sufficient space to engage in species-typical behavior, by providing enclosure complexities such as perches and swings, by providing manipulable objects (such as balls and other objects), and by varying the methods of feeding (such as allowing the primates to forage for food). The reports indicated that social interaction and exercise are equally necessary to promote their psychological well-being and that social grouping increases the primates' physical activity. The reports differed, however, in their recommendations of the precise means, or combination of means, considered necessary to promote the primates' psychological needs. Based on these reports and our observation of and experience with nonhuman primates, and considering the differences of opinion among the various professional communities maintaining nonhuman primates, we have determined that nonhuman primates have an acknowledged need for physical and mental stimulation, and that their needs can be met in various ways.

We have considered the environmental conditions under which nonhuman primates are maintained by regulated persons, and are proposing minimum standards for primary enclosures used by research facilities (including federal research facilities), dealers, exhibitors, and traveling or mobile animal act exhibitors. We have proposed four sets of minimum standards because the environment in which a nonhuman primate is maintained may satisfy some of its needs and may require providing other forms of stimulation or environmental enhancements to satisfy other needs. For example, grouping by families and compatible nonhuman primate species would meet the need for social interaction of primates maintained in permanent zoo exhibits, while creating other needs, such as the need of exhibited animals to have privacy from each other and from the public. In other cases, environmental conditions may restrict the opportunity to provide stimulation through otherwise accepted means because it may not be in the best interest of the primates' safety, health, and well-being to do so. For example, dealers may need to individually house newcomers if placing them in an enclosure with an established group would cause aggressive behavior among the other nonhuman primates. The psychological needs of the individually housed primates would have to be met through other means.

Accordingly, as explained in greater detail below, we are proposing that primary enclosures used to maintain nonhuman primates must provide sufficient space, as set forth in our proposal, and that nonhuman primates must have exercise, social interaction (or human interaction), and environmental enrichments, consistent with their safety, health, and well-being. The minimum amount of space that would be required for each nonhuman primate, and the kind and amount of other means of meeting psychological needs that would be required under our proposal would vary among the four sets of minimum standards and would depend upon all the forms and opportunities for physical and mental stimulation presented to nonhumn primates in the environments typically provided by research facilities, dealers, exhibitors, and mobile or traveling animal act exhibitors, respectively. Under our proposal, when an acknowledged means of providing the stimulation considered necessary for the primates' psychological well-being is amply supplied because of the environment in which the primates are maintained, other requirements for providing stimulation may be affected, as long as a sufficient amount and variety of stimulation is provided to meet the animals' psychological needs.

The proposed space requirements are minimum standards that must be provided to *each* nonhuman primate contained in a primary enclosure, unless otherwise specified. Consequently, if two nonhuman primates are housed together in one enclosure maintained by a research facility, the minimum floor area would be the sum of the minimum floor area space requirements that must be provided to each animal. The minimum height for the animal would likewise be increased, up to twice the greatest height required for any of the nonhuman primates contained in the primary enclosure but not to exceed 84 inches in height. This is because taller enclosures would not fit in most rooms and would not be necessary as long as each animal has a sufficient volume of space. Also, the proposed regulations would not allow the size of a primary enclosure to be reduced because it contains a suspended fixture, such as a swing or a perch.

1. Research facilities, federal research facilities

Our observations of nonhuman primates maintained in research facilities and the advice of the expert committee convened by APHIS, indicate that nonhuman primates used in research typically interact regularly with their human caretakers. Studies involving nonhuman primates often require observation by and physical contact with a principal investigator, perhaps several times each day. In fact, it has been shown that even intrusive procedures, such as drawing blood, are not stressful to chimpanzees maintained in research facilities, if performed by a familiar, trusted caretaker. Interaction with human caretakers, if a positive experience, is considered significant in alleviating distress under experimental conditions and helps promote the psychological well-being of nonhuman

primates maintained in research environments.

Although human interaction provides a primary source of stimulation to nonhuman primates maintained by research facilities, we have determined that other forms of physical and mental stimulation must also be provided. The need for environmental enrichments is explained under the heading, "Additional requirements for research facilities." Specific requirements are proposed in § 3.81, "Additional requirements for research facilities."

We have also determined that nonhuman primates need greater space than that required under the current regulations, so that they can engage in species-typical physical activity that is necessary for their psychological well-being. As stated above, the minimum space requirements we are proposing must be provided to *each* nonhuman primate in an enclosure. Accordingly, nonhuman primates maintained in groups will have larger enclosures in which to engage in physical activity. Communally-housed primates engage in increased physical activity, prompted by their interaction. Those housed individually will have to be released into larger primary enclosures (at least three times the minimum area and twice the minimum height up to 84 inches) for exercise unless they are housed in primary enclosures that provide twice the minimum volume required. This release requirement is also explained in greater detail under the heading, "Additional requirements for research facilities."

We are proposing minimum primary enclosures space requirements that we consider sufficient to promote the psychological well-being of nonhuman primates, in light of the social interaction they receive and the additional environmental enhancements that must also be provided. The minimum enclosure sizes proposed are based on the typical weight of the species, except for brachiating species, in accordance with the following table:

Group	Weight		Floor Area/Animal		Height	
	lbs.	(kg.)	ft.²	(m²)	in.	(cm.)
1	2.2	(1)	1.6	(0.15)	20	(50.8)
2	2.2–6.6	(1–3)	3.0	(0.28)	30	(76.2)
3	6.6–20.0	(3–10)	4.3	(0.40)	30	(76.2)
4	20.0–33.0	(10–15)	6.0	(0.56)	32	(81.28)
5	33.0–55.0	(15–25)	8.0	(0.74)	36	(91.44)
6	55.0–88.0	(25–40)	25.1	(2.33)	84	(213.36)
7	>88.0	(>40 kg.)	50.0	(4.65)	84	(213.36)

The proposed enclosure sizes are similar to those provided in the NIH Guide, except that the NIH Guide categorizes nonhuman primates by weight into six categories, combining Groups 6 and 7 into one category for all nonhuman primate species over 55.0 pounds. We do not believe it would be appropriate to require the same minimum floor area and height for the larger great apes weighing over 88.0 pounds, such as gorillas, as for the smaller great ape species, since the former are substantially larger in size and consequently require more space for their psychological well-being. Our decision to propose seven weight groups for determining minimum space requirements is in accordance with the recommendations we received from the expert committee on nonhuman primates.

The proposed minimum floor area and height that must be provided by research facilities, including federal research facilities, were also recommended by the committee as sufficient to promote the psychological well-being of nonhuman primates.

Nonhuman primates would be categorized into these seven groups by the typical weight of animals of their species, except for infants (up to 6 months of age) and juveniles (6 months to 3 years of age) of various species that may weigh so much less than adults of their species that they are grouped with lighter weight species unless they obviously require greater space to make normal postural adjustments and movements, and except for brachiating species. Brachiating species are those that typically hang or swing by their arms so that they are suspended in the air and fully extended. The following are examples of the types of nonhuman primates that fall into each group:

Group 1—Marmosets, Tamarins, and infants of various species.

Group 2—Capuchins, Squirrel Monkeys and species of similar size, and juveniles of various species.

Group 3—Macaques and African species.

Group 4—Male Macaques and large African species.

Group 5—Baboons and nonbrachiating species larger than 33.0 lbs. (15 kg.).

Group 6—Great Apes up to 88.0 lbs. (40 kg.) and brachiating species.

Group 7—Great Apes greater than 88.0 lbs. (40 kg.).

We determined it appropriate to provide guidelines to research facilities by proposing these seven weight groups. In most instances, the specified dimensions for the various species will be sufficient to promote the primates' psychological well-being, and the table can be used to determine the minimum space requirements for each species. However, if a nonhuman primate is unable to make normal postural adjustments and movements, or cannot do so without difficulty, notwithstanding the table, it must be provided greater space.

We encourage the design and development of pimary enclosures that promote the psychological well-being of nonhuman primates by providing them with sufficient space and unrestricted opportunity for movement and exercise, and by allowing them to interact physically and socially with other nonhuman primates. Accordingly, we are proposing to allow the use of primary enclosures that do not precisely meet the space requirements otherwise required of research facilities upon application to the Administrator for permission. An applicant would be required to demonstrate both in writing and through use of photographic aids that the proposed primary enclosure provides sufficient space and is designed so that the nonhuman primates can express species-typical behavior. The Administrator would grant the application if he or she determines it meets our requirements for promoting the psychological well-being of the nonhuman primates, or would deny it if he or she determines that it is detrimental to the health and psychological well-being of the nonhuman primates proposed to be housed in the enclosure. The nonhuman primates housed in the enclosure would be excused from the required social release period required in proposed

§ 3.81(a)(3) if the applicant demonstrates that the primary enclosure is designed and constructed in a manner that provides for the nonhuman primates' psychological well-being by allowing them sufficient exercise and social interaction.

Additional requirements are imposed upon research facilities to provide environmental enrichments whenever possible in accordance with the mandate of the Act, as amended, and Part 2 of the Animal Welfare regulations. Since there are unique considerations in many instances because of the necessities of animal care and use procedures, we are proposing to place these additional requirements in a separate section, proposed § 3.81, which follows this discussion of minimum space and environmental requirements. We believe that the space requirements of proposed § 3.80(c)(1) together with the requirements proposed in § 3.81 will promote the psychological well-being of nonhuman primates used in research.

2. Dealers

From our experience in regulating dealers, we have determined that dealers obtain nonhuman primates from various parts of the country and the world. These nonhuman primates are of various species and may have been transported individually or with an established group. In most instances, the time period nonhuman primates are held by dealers is relatively brief. Generally, dealers hold the animals until they are sold, which usually occurs quickly, or until arrangements are made for transferring them to their new owner. Accordingly, nonhuman primates maintained by dealers are typically subject to the stresses of travel and transiency.

Unlike nonhuman primates maintained by research facilities, that have been conditioned so that their health status is stable and known, newly imported are transported nonhuman primates can carry disease organisms requiring quarantine and/or veterinary care. Some may carry disease organisms that do not affect it, but that may affect others primates of the same species from different locales, and other species that may be suspectible. This risk exists even after they have completed a quarantine period. In addition, the stress of shipment makes them more susceptible to disease. Accordingly, health concerns frequently require that nonhuman primates be individually housed, to promote their well-being. These concerns would not impact upon established groups, since all the animals in the group would have been exposed to the same disease hazards and would generally have the same immunities.

Established groups of nonhuman primates are known to have defined social structures, with dominant animals at the head of the pecking order. When new primates of the same or different species are introduced into an established group, aggression among the primates frequently results as they attempt to establish the newcomer's status in the social structure. This aggressive behavior is dangerous for the nonhuman primates and for their caretakers. We believe that the hazards attendant to altering the social composition of an established group for what is generally a brief period may require that individual nonhuman primates obtained by dealers be housed apart from established social groups for the primates' safety, and that they should not be introduced into the group.

Accordingly, we believe that these health and safety concerns justify requiring that nonhuman primates' needs be met through means that do not include physical interaction with other nonhuman primates, in accordance with the determination of the attending veterinarian, unless the primates are part of an established group. Under our proposal, dealers would remain subject to the requirements of paragraph (b), "Social grouping," and must ensure that individually housed nonhuman primates can see and hear other nonhuman primates of their own or compatible species, or have positive physical contact or other interaction with their keeper or other familiar and knowledgeable person for at least one hour a day.

Because social interaction among nonhuman primates maintained by dealers may be restricted for health and safety reasons, we would require that dealers provide multiple enrichments of the physical environment of the primary enclosures that are appropriate for the nonhuman primates' species and age, in order to satisfy the animals' psychological needs. The proposed enrichments are essential for providing sufficient physical and mental stimulation to the nonhuman primates, particularly if they are individually housed. Examples of enrichments we would require include providing perches, swings, mirrors, or other increased cage complexities; providing toys, balls, and objects for the animals to play with or manipulate; and varying the method of feeding to make it more interesting to the primates or to stimulate feeding in nature. We would require multiple enrichments for each animal housed in a primary enclosure.

We are proposing minimum space requirements for individually housed nonhuman primates held by dealers that are twice the minimum floor area and twice the minimum height (up to a maximum of 84 inches) that research facilities would be required to provide. We believe the increase in minimum space requirements over that required of research facilities is necessary to promote physical activity because individually housed nonhuman primates may not be released for exercise and are not as active as those housed in social groups. The reader should note that nonhuman primates maintained in research facilities housed in enclosures providing twice the minimum floor area and twice the minimum height, up to a maximum of 84 inches, are not required to be released for exercise under our proposal. Nonhuman primates held by dealers also have less social interaction with other species than those maintained in research facilities, for reasons cited above, and have less interaction with humans. Increasing the required minimum space will provide an opportunity for greater physical activity and stimulation.

We would require that nonhuman primates housed in pairs, families, or other social groups be provided the same minimum space as research facilities would be required to provide. Unlike the requirements we are proposing for individually housed nonhuman primates, we are not proposing to require twice the minimum space that research facilities must provide to pairs, families, or other social groups, because the nonhuman primates will receive increased physical and mental stimulation through interaction with other group members.

The different species of nonhuman primates would be categorized into the same 7 groups as for research facilities. Because of the increased space provided, the brief time they are held by dealers, and the health and safety reasons cited above, we would not require that the animals be released for exercise or social interaction.

The proposed regulations would allow dealers to provide the same minimum space required of research facilities under certain specifically identified circumstances, when necessary. These purposes are limited to: holding the animal for a required quarantine period, having the animal receive veterinary care as directed by the attending veterinarian, and transporting the animal to or from an auction sale and holding it at the sale. All of these

occasions would be brief. Based on our observation of and experience in regulating dealers we believe that it is necessary to restrict the animals' space under these circumstances so that the dealers can properly observe and handle the nonhuman primates. It would also reduce the possibility of injury to both the nonhuman primate and its handler. The requirement to provide environmental enrichments would remain in full force to provide for the animals' psychological needs during these short-term periods.

3. Exhibitors

We believe that many of the psychological needs of nonhuman primates maintained in zoos are satisfied because they are housed in primary enclosures in social groups in more naturalistic environments. Because of their communal housing they have greater opportunity for physical activity and mental stimulation. Perches and climbing structures are often provided to them in their naturalistic environment so that the viewing public can observe their species-typical behavior. However, we have determined, based upon the information available to us, that their environment necessitates environmental enrichments to accommodate other needs in promoting their psychological well-being. For example, some species of nonhuman primates maintained in permanent zoo exhibits may require privacy and refuge from the public, and from each other, as a result of daily public exposure. Also, unlike nonhuman primates maintained by research facilities and dealers, primates maintained in permanent zoo exhibits are encouraged to mate and reproduce. It has been scientifically shown that nonhuman primates in psychological distress do not engage in normal reproductive behavior. Accordingly, their physical environment must be enriched to promote their psychological well-being, so that they may do so.

We are proposing minimum space and environmental enrichment requirements that are similar to this recommendations presented to us by the American Association of Zoological Parks and Aquariums (AAZPA) in its report. This study was compiled at our request and was the result of a collective effort of a committee of AAZPA members. The AAZPA study categorizes nonhuman primates into seven groups based upon the known social behavior of the animals, as opposed to typical weight of the species. Each nonhuman primate species has different needs, based upon its typical social behavior and physical activity that must be satisfied for their psychological well-being in a zoo or exhibition environment.

The minimum space, environmental enrichments, and social grouping required in the proposed regulations for each group of nonhuman primates is based upon our experience in regulating exhibitors and the industry's recommendations after observation of and experience with the animals. We believe they will be appropriate to promote the psychological well-being of each of the species.

The specific minimum space and environmental requirements are set forth in the rule portion of this document at proposed § 3.80(c)(3), and appear in chart form. The chart divides the various species into 7 groups and offers examples of the types of nonhuman primates included in each. For each grouping, the chart specifies the minimum number of nonhuman primates to be housed together in a primary enclosure, the minimum space requirements for that group, whether shelters are required and if so how many and of what size and the furnishings that are required to enrich the environment in the primary enclosure and provide for the animals' psychological well-being. Except for great apes, we are proposing minimum space requirements for groups of nonhuman primates, in accordance with the AAZPA recommendations, and not for individual animals.

4. Mobile or traveling animal act exhibitors

Our proposal for minimum space and environmental requirements applicable to mobile or traveling animal act exhibitors is in two parts. One part pertains to nonhuman primates that participate daily in animal acts, shows, or training periods outside of their primary enclosure. The second pertains to nonhuman primates that are permanently contained in their primary enclosure. We are proposing regulations in accordance with these two classifications because we have determined, based upon observation and our experience in regulating mobile or traveling animal act exhibitors, that animals used in trained animal acts are generally released daily for training or for performances, except during brief layovers between shows, and that untrained animals are used primarily for public exhibition and are not released. We are not aware of any nonhuman primates used in traveling exhibitions that would justify proposing an additional set of requirements.

Trained, performing nonhuman primates receive a great deal of mental and physical stimulation on a daily basis. Their lives are enriched and varied through multiple performances on a daily basis, and training sessions in between. When performing, the primates are in a close, working relationship with their trainer, and with any other animals in the act. Between performances, the nonhuman primates are given training sessions to sharpen their performances and to learn new routines. We believe that these nonhuman primates' psychological needs are met by their interaction and activity. Accordingly, we do not consider it necessary to require additional environmental enrichments in their primary enclosures. We are proposing in § 3.80(c)(4)(i) that mobile or traveling animal act exhibitors provide the minimum space required of research facilities. We believe this space is sufficient to promote the psychological well-being of the nonhuman primates when they are contained in primary enclosures.

Nonhuman primates used in mobile or traveling animal act exhibits that are not trained and are used for static or stationary exhibits do not receive daily interaction with their caretakers, unlike those maintained in research facilities. Often they are solitary exhibits, such as gorillas held for public viewing, and do not interact with other nonhuman primates. Unlike the nonhuman primates held by dealers, the animals are maintained under these circumstances for long periods, without being released, and therefore require more environmental stimuli and opportunities for physical activity to promote their psychological well-being than nonhuman primates maintained by research facilities, dealers, and exhibitors. We are therefore proposing to require multiple environmental enrichments that allow the different species of nonhuman primates to engage in species-typical behavior. The enrichments required would be similar in kind to those that dealers and exhibitors are required to provide, and they too must be appropriate for the species and age of the animal. We are proposing that the minimum space that must be provided to these nonhuman primates be at least three times the floor area and twice the height (up to a maximum height of 84 inches) that research facilities are required to provide. We believe that enclosures providing this minimum space would be appropriate for housing up to three nonhuman primates under these circumstances, since their social interaction will provide greater opportunity for physical stimulation. The minimum space provided would be required to be increased in accordance

with paragraph (d) of proposed § 3.80 for each additional 1–3 nonhuman primates also housed in the primary enclosure. We believe that the increased minimum space is necessary to encourage and allow greater physical activity and would also be consistent with highway travel restrictions. We believe that if these requirements are met, the psychological needs of these nonhuman primates will be satisfied.

Except where otherwise stated, the minimum space requirements provided in proposed § 3.80(c) are mandatory for each individual nonhuman primate housed in a primary enclosure. Accordingly, the minimum space provided must be increased when nonhuman primates are housed in multiples in a primary enclosure so that each has a sufficient volume of space in which to express species-typical behavior since overcrowding is known to result in nonhuman primates becoming agitated and to cause them to express abnormal behavior. We are proposing to require that primary enclosures be increased in size by the floor area required for each nonhuman primates if it were housed individually and that the minimum height provided by twice that required for the largest nonhuman primate in the enclosure, up to a maximum height of 84 inches. We are not proposing to require that the minimum height provided be increased for each additional animal housed in the primary enclosure since the enlarged area coupled with the doubled height should provide sufficient volume for the nonhuman primates' activity. Also, the maximum height ceiling of 84 inches is a practical limitation since enclosures of greater height would not fit in many rooms.

Based upon the cited authorities and our experience, we believe that these proposed minimum space and environmental enrichment requirements are sufficient to promote the psychological well-being of nonhuman primates maintained by regulated persons.

Variance

We understood that the proposed minimum space requirements for nonhuman primates might require persons subject to the Animal Welfare regulations to rebuild or remodel their facialities and to expend previously unanticipated and unbudgeted monies for new primary enclosures and fixtures. In some instances major structural modifications might be required in order to satisfy the proposed space requirements. Until the necessary adjustments were made, many registrants and licensees would not be in compliance with the proposed requirements.

In cases where the effective date of the regulations would not coincide with a facility's fiscal years, we are aware that budget planning and funding procedures for the next fiscal year would take some time. Once funds have been appropriated, facilities would require additional time to make the necessary space modifications. To allow facilities sufficient time to conform with the proposed minimum space requirements, we are proposing to include a mechanism for issuing variances to eligible persons. This mechanism would be similar to that already in place for licensees and registrants in Subpart E—"Specifications for the Humane Handling, Care, Treatment and Transportation of Marine Mammals."

A "variance" would be issued, in writing, by the Administrator of APHIS, and would allow an eligible registrant or licensee to continue operating even though not fully in compliance with the minimum space requirements for nonhuman primates. A variance would be limited to the proposed minimum space requirements. It would not allow noncompliance with the proposed environmental enrichment, social grouping, and release requirements; these requirements would have to be complied with upon the effective date of the regulations. The variance would be limited in scope both as to time and to the primary enclosures covered by it, and would specify the portions of the applicant's facilities to which it applied.

Registrants and licensees maintaining or handling nonhuman primates, having nonhuman primates on their premises or under their control or supervision, and not complying with the minimum space requirements proposed in § 3.80, would have to apply for a variance. Facilities that are under construction or that are in the design or preliminary construction stages on the date these regulations become effective, would not be eligible for a variance since they could adapt their construction to comply with them. However, a facility that was so nearly complete that it would require substantial modification at a previously unbudgeted and significant cost to bring it into compliance would be eligible for a variance.

A variance could be granted, at the sole discretion of the Administrator, for up to 2 years. We believe that this would allow sufficient time for a registrant or licensee to raise the necessary funds and to contract for the required work, as well as to purchase whatever fixtures or equipment were necessary for it to comply with the minimum space requirements. One extension of up to 1 year could be granted by the Administator if he or she determined that it was necessary, based upon the facts presented in the application for an extension. The extension would be granted if justified due to unforeseen situations that prevented full compliance during the variance period. As an example, unforeseen circumstances for research facilities could be nonallocation of public funds to make the necessary expenditures.

An application for a variance would be required within 60 days of the effective date of these regulations and would have to be in writing. According to the proposed regulations it must list, in detail, specific reasons why the variance was being requested, and each of the minimum space requirements the facility cannot meet. It must identify the species and number of nonhuman primates that would be affected by the variance, and must state the amount of time necessary for the applicant to come into compliance and the estimated cost of compliance.

We are proposing to require a statement from the attending veterinarian concerning the age and health status of the nonhuman primates affected by the variance, and addressing whether granting the variance would be detrimental to the affected nonhuman primates.

As is presently the case for marine mammals, the Administrator could require the submission of an outside independent expert report, if the Administrator believes it would assist him or her in determining whether the granting of a variance would be detrimental to the health and psychological well-being of the affected nonhuman primates. The applicant would bear the cost of the expert report.

The Administrator would grant an application for a variance if he or she determined it was justified, or would deny it if he or she determined that it was not justified or that granting it would be detrimental to the health and psychological well-being of the nonhuman primates affected. The grant or denial would be in writing. The applicant could request that the Administrator reconsider his or her decision to deny an application, in accordance with the requirements of § 3.80(e)(4). Similarly, a request for an extension would be granted by the Administrator if he or she determined that it was justified, or denied if he or she determined that it was not justified or that granting it would be detrimental

to the health and psychological well-being of the nonhuman primates affected. The grant or denial of the extension would also be in writing. The applicant could request that the Administrator reconsider his or her decision to deny an application for an extension, in accordance with the requirements of § 3.80(e)(5). If the extension were granted upon reconsideration, it would be retroactive to the termination date of the initial variance.

Variances would be revocable for bad faith, such as a false representation on the initial application or in the request for extension. They could also be revoked if the purposes for which they were issued were not being carried out, or if they were detrimental to the health and psychological well-being of the nonhuman primates affected.

Additional requirements for research facilities

In proposed § 3.81, "Additional requirements for research facilities," we are proposing environmental enrichments that research facilities would be required to provide, in addition to the minimum space requirements contained in proposed § 3.80(c)(1). We are doing so because the Animal Welfare Act, as amended, and the regulations contained in Part 2 of the Animal Welfare regulations (*see* companion docket no. 88-014, published elsewhere in this issue of the Federal Register impose specific duties on research facilities holding animals for research, testing, or teaching that are not imposed upon other regulated persons or industries, and that can affect their determination of the specific means employed to promote the psychological well-being of nonhuman primates. For example, § 2.30(h) requires that research facilities provide for the psychological well-being of nonhuman primates in accordance with the regulations and standards and that they maintain a record system indicating that they are complying with the regulations. Also, under the regulations in Part 2, Subpart C—"Institutional Animal Care and Use Committee and Other Requirements for Research Facilities," each facility's Committee must, among other things, review and approve a proposed animal care and use procedure [ACUP] before research, testing, or teaching can commence, inspect the facility for compliance with these regulations in accordance with § 2.35, and report deficiencies. Research facilities must also establish a written policy ensuring that the attending veterinarian is consulted in ACUP planning and development. Accordingly, in addition to prescribing the environmental enrichments that research facilities would be required to provide, proposed § 3.81 includes reference to the role of the Committee and the attending veterinarian in promoting the psychological well-being of nonhuman primates.

After considering all the information available to us, including the report of the expert committee on nonhuman primates, we are proposing the following minimum requirements to promote the psychological well-being of nonhuman primates in accordance with the Act, as amended. These requirements are in addition to the minimum space requirements set forth in proposed § 3.80(c)(1).

As explained above under the heading, "Space and physical environment," many of the psychological needs of nonhuman primates used in research facilities are met through their regular interaction with their human caretakers. However, we believe that environmental enrichments must also be provided by research facilities so that the primates can engage in species-typical behavior and receive sufficient physical and mental stimulation at all times. Proposed § 3.81(a)(1) provides examples of the kinds of enrichments that would be required under our proposal. These include: (1) Perches, swings, mirrors, and other cage complexities; (2) toys or objects to manipulate; and (3) varied methods of feeding. We would require a combination of environmental enrichments and that at least one form of enrichment from each type listed be provided. Proposed § 3.81 would also require that research facilities house nonhuman primates in social groupings in primary enclosures whenever possible, to increase their physical activity and for their psychological well-being.

We are proposing additional requirements applicable to individually housed nonhuman primates. In order to ensure that these primates have sufficient opportunity for physical activity, we would require that they be released for at least four hours of exercise each week into an area that has at least three times the floor area and twice the height of their primary enclosure. Release would not be required if they are maintained in a primary enclosure with other nonhuman primates, or if they are maintained in a primary enclosure that is at least twice as great as that required for the species, because they would have greater opportunities to engage in physical activity on an ongoing basis. Under our proposal, nonhuman primates may be placed with compatible species during the required release period. This social interaction would promote their psychological well-being and is known to increase their physical activity.

Proposed § 3.81(a)(4) would also require research facilities to provide for the special psychological needs of individually housed nonhuman primates that are infants or juveniles, that are used in research that does not provide for much activity, and those showing signs of psychological distress. We would require that they consult with the attending veterinarian who would instruct the facility as to the additional environmental enrichments that must be provided to provide for the primates' psychological well-being. These three categories of nonhuman primates are specifically identified in the proposed regulations because we concur with the expert committee on nonhuman primates that they require additional consideration of their needs to promote their psychological well-being. Infants and juveniles are in the formative period of their developmental growth and require physical and mental stimulation for normal development. They also require social interaction with other nonhuman primates so that they can function in accordance with the typical social behavior for their species. Similarly, those required to be inactive lack the physical activity and stimulation considered important for their psychological well-being, and their needs must be provided for in different ways. The special needs of those showing signs of psychological distress must also be individually addressed to prevent the development of psychological disorders. Because the needs and circumstances of individually housed nonhuman primates falling under any of these categories will differ on an individual basis, we believe it is appropriate to require that research facilities consult with their attending veterinarian, who has expertise in the care and treatment of the species being attended, and can prescribe the additional measures deemed necessary to satisfy the primates' psychological needs. We would require the attending veterinarian to keep records of these additional instructions, and they would be subject to APHIS inspection under proposed § 3.81(c).

We are proposing to add a prohibition against confining nonhuman primates in chairs, unless required by an animal care and use procedure and approved by the Committee in accordance with Part 2 of the Animal Welfare regulations, and unless the animal is

released daily for exercise for at least one continuous hour each day during the period of confinement unless continuous restraint in a chair is required by an animal care and use procedure and approved by the Committee. If continuous restraint is approved we are proposing to require that the nonhuman primate be released for exercise for at least one hour before and one hour after the period of restraint. We are proposing to include this prohibition because of the importance of physical activity in promoting the psychological well-being of nonhuman primates.

The proposed regulations would also require that documentation of the release of nonhuman primates and of additional environmental enrichments ordered under paragraph (a)(4) be kept by the attending veterinarian, subject to inspection by APHIS inspectors, and in the case of federal research facilities, to review by officials of any federal funding agency. These records would also be subject to inspection by the Committee in accordance with the regulations in Part 2. (*See* companion docket no. 88–014, published elsewhere in this issue of the **Federal Register.**)

We recognize that certain situations will require an immediate response from facility personnel when it is necessary to provide less than the minimum standards to a nonhuman primate, due to the condition of the animal, in order to provide for its welfare. We are proposing to include a provision in proposed § 3.81 that would authorize attending veterinarians to exempt or restrict a particular nonhuman primate from its required exercise and social release period if he or she determines that it is necessary for the nonhuman primate's health, condition, or psychological well-being due to the physical or psychological condition of the animal. The exemption would be for a period of up to 30 days and must be recorded by the attending veterinarian and subject to APHIS inspection and in the case of federal research facilities, to review by officials of any federal funding agency. We would require that the research facility be responsible for having the attending veterinarian review the grant of exemption at least every 30 days to determine if it is still warranted under the circumstances. Exemptions would be required to be included in the research facility's annual report and in the Committee's inspection report under § 2.35(b)(2)(i)(C). (*See* companion docket no. 88–014, published elsewhere in this issue of the **Federal Register.**) We believe that this exemption procedure would fill the need to have short-term authorization for deviation from these proposed standards due to unusual or unanticipated circumstances.

Feeding

We are proposing to revise the provisions of current § 3.79 "Feeding," to include means of enhancing the psychological well-being of nonhuman primates by varying the types of food and the methods of feeding, such as by using task-oriented feeding or allowing the animals to forage for food as in nature. We believe that requiring variation in the nonhuman primates' feeding on a daily basis is a necessary means of providing necessary mental and physical stimulation.

Proposed § 3.82 would require multiple feeding sites if members of dominant nonhuman primate or other species are fed together with other nonhuman primates and would require observation of the feeding practices of the animals to determine that each receives a sufficient amount of food. We believe that this will also enhance the psychological well-being of nonhuman primates by ensuring that each has access to food and will not be prevented from obtaining food due to the aggressive behavior of others.

We are proposing minor changes to current § 3.79 to provide that the amount of food, type of food, and frequency of feeding must be appropriate for the species, size, age, and condition of the nonhuman primate, and must be in accordance with generally accepted professional and husbandry practices and nutritional standards. In accordance with those practices and standards, consideration would also be given to the conditions under which the animal is kept, such as whether it is maintained in a primary enclosure allowing it frequent vigorous activity or if it is maintained in a primary enclosure that is more limiting, and whether it is maintained outdoors in a cold environment or in a warm environment, since these variables may affect the amount of food that is appropriate for the animal. Also, in accordance with Part 2 of the Animal Welfare regulations, any deviation from these standards due to the necessities of research must be justified by an animal care and use procedure approved by the facility's Committee. (See companion docket no. 88–014, published elsewhere in this issue of the **Federal Register.**)

Proposed § 3.82 would also require that nonhuman primates be fed at least once each day unless otherwise required to provide adequate veterinary care to the animals.

We would continue to require sanitization of food containers at least once every two weeks and would also require that food containers be sanitized anytime they are used to provide food to a different nonhuman primate or social grouping of nonhuman primates. Approved methods for sanitization would be those methods provided in proposed § 3.84(b) for sanitization of primary enclosures.

Watering

We are proposing minor changes to current § 3.80 to require that sufficient potable water be provided to the nonhuman primates. We are retaining the requirement that if water is not available to the nonhuman primates at all times, it must be offered to them at least twice a day and we are proposing to add a requirement that the water be offered for at least one hour each time it is offered. The attending veterinarian could vary these requirements if he or she determines it is necessary to provide adequate veterinary care to the nonhuman primates. The proposed regulation would continue to require sanitization of water containers at least once every two weeks and would also require sanitization when used to provide water to a different nonhuman primate or social grouping of nonhuman primates. Approved methods of sanitization would be those methods provided in proposed § 3.84(b)(3) for sanitization of primary enclosures.

Cleaning, sanitization, housekeeping, and pest control

In proposed § 3.84 we are proposing requirements similar to those in current § 3.81 concerning cleaning, sanitization, housekeeping, and pest control, in order to provide for the welfare and well-being of nonhuman primates. The proposed revisions to current § 3.81 include requiring removal of excreta and food waste from primary enclosures and from pans underneath primary enclosures with grill-type floors at least daily and as often as necessary, rather than merely "as often as necessary" as in the current regulations, and requiring removal of the animals from a primary enclosure when a cleaning method using water is performed so that they will not be involuntarily wetted or injured. We are proposing to require that fixtures inside of primary enclosures, such as bars and shelves, must be kept clean and be replaced when worn. In addition to requiring sanitization of planted areas inside of primary enclosures and gravel, sand, and dirt surfaces by removing contaminated material, the proposed regulations would require that they be raked and spot cleaned daily. As explained above under the heading "Facilities, general" if the nonhuman primates engage in scent marking, the

primary enclosures must be spot cleaned daily and sanitized at regular intervals established in accordance with generally accepted professional and husbandry practices, so as not to cause those animals psychological distress.

We believe that these additional requirements will enhance the physical environment in which nonhuman primates are maintained through cleanliness and that they are necessary for their general welfare.

We are proposing nonsubstantive changes to current subsections (a)–(d) for purposes of clarity. We believe that these clarifications will make the regulations easier to understand and comply with.

Employees

Current § 3.82 requires that there be a sufficient number of employees to maintain the prescribed level of husbandry practices required by Subpart D and the rendering of husbandry practices be under the supervision of an animal caretaker with a background in animal husbandry or care. We are proposing minor revisions to this section in proposed § 3.85 to make clear that this requirement is imposed upon every person subject to the Animal Welfare regulations, and that the burden of making certain that the supervisor is appropriately qualified is on the employer regulated under the Act. We are not proposing to prescribe a specific number of employees for each facility, because the number of employees needed will vary according to the size and configuration of the facility, and according to the number and type of animals housed there. We would require that a facility have enough employees to carry out proper feeding, cleaning, observation, and other generally accepted professional and husbandary practices.

Social grouping and separation

We are proposing to revise current § 3.83 concerning social grouping of nonhuman primates in primary enclosures in order to promote their psychological well-being. The current regulations provide that when nonhuman primates are housed together they must be maintained in compatible groups and must not be housed in the same enclosure with animal species other than nonhuman primates. We are proposing to allow nonhuman primates to be housed with other nonhuman primate species and with other animal species as long as they are compatible, do not compete with the other species for food and shelter, and will not be hazardous in any way to the health and well-being of each other.

We are proposing to add the following regulations requiring separation of nonhuman primates in the following circumstances: (1) Nonhuman primates exhibiting vicious or overly aggressive behavior must be housed separately and (2) nonhuman primates under quarantine or treatment for a communicable disease must be housed separately. We believe the requirements to house nonhuman primates separately under these limited circumstances are necessary to allow nonhuman primates to peacefully coexist in primary enclosures, as is required for their psychologial well-being, and to protect their physical health and welfare.

The proposed regulations would include provisions for keeping families together and for keeping compatible groups constant. This is because studies of nonhuman primates have shown that they are socialized in a family-oriented manner in nature and that varying a group's composition may lead to distress or aggressive behavior towards new members of the group. Accordingly, we believe these regulations are necessary to promote the psychological well-being of nonhuman primates.

Transportation standards

In preparing our proposal to amend the transportation standards we consulted the "Interagency Primate Steering Committee Guidelines" developed by the United States National Institutes of Health-sponsored Interagency Primate Steering Committee. The Interagency Primate Steering Committee is composed of an inter-agency group of scientists concerned with the care and handling of nonhuman primates. The introduction to the Guidelines states the following:

> Shipment of nonhuman primates by a carrier from one location to another is stressful, even under the best of conditions. The purpose of these guidelines is to minimize the effects of transportation stress on these animals and to have them arrive at their destination in as good a physical condition as possible, with a minimal degree of illness or mortality. Secondly, the guidelines are intended to serve as a reference for adequate care of nonhuman primates for all persons involved with the shipping of these animals.

We also considered the transportation standards proposed by the U.S. Department of the Interior, Fish and Wildlife Service (USFWS) for nonhuman primates imported from abroad.

Based upon our experience enforcing the current regulations, and our consideration of the information available to us, we are proposing the following revisions to the transportation standards in order to safeguard the health, safety, and psychological well-being of nonhuman primates transported in commerce.

As part of this revision, we are proposing to include requirements that were previously part of the Animal Welfare regulations but were inadvertently omitted from the 1977 revision of the regulations. When the transportation standards were rewritten in 1977 to incorporate the 1976 amendments to the Act concerning the commercial transportation of animals, the existing standards for surface transportation were not included in the regulations. Since that time, the standards have pertained to the commercial transportation by common carrier and only a few subsections have pertained to surface transportation by private vehicle. This omission has caused numerous difficulties in the enforcement of standards regarding surface transportation of nonhuman primates and in the prosecution of persons who have improperly handled and transported nonhuman primates by private surface vehicle. The reinstated regulations particularly affect provisions concerning ambient temperature specifications during surface transportation that should result in improved traveling conditions for nonhuman primates. They also impose similar requirements on all persons subject to the Animal Welfare regulations engaged in the transportation of nonhuman primates, so that the animals will be afforded necessary protections whenever they are transported in commerce.

Consignments to Carriers and Intermediate Handlers for Transportation

The current obligations imposed upon carriers and intermediate handlers (defined in Part 1 of the regulations and published elsewhere in this issue of the Federal Register) would be expanded to ensure the well-being of nonhuman primates during transport in commerce. Certain prerequisites must be satisfied before carriers and intermediate handlers may accept nonhuman primates for transport in commerce. Additionally, the carriers and intermediate handlers have certain duties to fulfill after the shipment has reached its destination. Various obligations are presently contained in current §§ 3.85 and 3.88. We are proposing to consolidate them in one section, proposed § 3.87, and to add some additional ones that are necessary for the nonhuman primates' welfare.

The reader should note that our proposed regulations do not specifically

refer to operators of auction sales, unlike the current regulations. The definition of the term "dealer" was amended in 1976 to include any person who "negotiates the purchase or sale" of animals for research, teaching, exhibition, or use as a pet. Operators of auction sales are therefore dealers. However, we did not remove the reference to them in the 1977 amendments to the regulations. We are proposing to do so now, to clarify the regulations. Accordingly, all references to dealers in the regulations would include operators of auction sales.

In sum, the requirements imposed on carriers and intermediate handlers in current § 3.85 are as follows: (1) Current § 3.85(a) requires that carriers and intermediate handlers not accept a live nonhuman primate for shipment from any person subject to the regulations more than 4 hours before the scheduled departure time of the primary conveyance in which the animal will be shipped, except that this time may be extended by agreement to 6 hours if specific prior scheduling of the shipment has been made. (2) Current § 3.85(b) requires that carriers or intermediate handlers accept a nonhuman primate for shipment only if it is in a primary enclosure meeting the requirements of current § 3.85, "Primary enclosures used to transport live nonhuman primates," except that they may accept a nonhuman primate if it is consigned by a person subject to the regulations who provides a certificate stating that the primary enclosure conforms with § 3.85, unless the enclosure is obviously defective. The information required to be in the certificate is stated in the regulation. Current § 3.85(c) states that carriers and intermediate handlers whose facilities do not meet the minimum temperature requirements provided in the regulations may accept a nonhuman primate for transport if the consignor furnishes a certificate executed by a veterinarian accredited by USDA within 10 days before delivery of the animal for transport stating that the nonhuman primate is acclimated to air temperatures lower than those prescribed in current §§ 3.90 and 3.91. The information required to be in the certificate is likewise stated in the regulation. Current § 3.85(d) requires carriers and intermediate handlers to notify the consignee of the animal's arrival at least once every 6 hours following arrival of the nonhuman primate at the animal holding area of a terminal facility and to record the time, date, and method of attempted and final notification on the shipping document.

Current § 3.88 requires the following: (1) § 3.88(a) requires that nonhuman primates be offered potable water within the four hours preceding transport in commerce. Dealers, exhibitors, and research facilities are required to provide water to nonhuman primates transported in their own primary conveyance at least every 12 hours after transportation is begun and carriers and intermediate handlers are required to do so at least every 12 hours after they accept the animal for transport.

(2) Current § 3.88(b) provides requirements concerning the frequency of feeding nonhuman primates and similarly distinguishes between those persons transporting nonhuman primates in their own primary conveyances, and carriers and intermediate handlers.

(3) Current § 3.88(c) requires any dealer, research facility, exhibitor, or operator of an auction sale consigning nonhuman primates for transport to affix written instructions concerning the animals' food and water requirements on the outside of the primary enclosure used for transporting the nonhuman primate.

(4) Current § 3.88(d) states that no carrier or intermediate handler shall accept a nonhuman primate for transport in commerce unless written instructions concerning food and water requirements are affixed to the outside of its primary enclosure.

We are proposing to place the various prerequisites that must be satisfied before carriers and intermediate handlers can accept a nonhuman primate for transport in commerce in proposed § 3.87, and to add some additional ones that are necessary for the nonhuman primates' well-being. We are also proposing nonsubstantive changes to current § 3.85(a) in proposed § 3.87(a).

Proposed § 3.87(c) would contain the requirements of current § 3.88(d) by requiring that written instructions concerning the food and water requirements for each nonhuman primate in the shipment be securely attached to the outside of the primary enclosure before a carrier or intermediate handler may accept it for transport.

As stated above, current § 3.88(a) provides that nonhuman primates must be provided water at least every 12 hours after acceptance by carriers and intermediate handlers for transportation. Current § 3.88(b) provides that nonhuman primates more than 1 year of age be offered food at least once every 24 hours after acceptance by carriers and intermediate handlers for transportation and that nonhuman primates less than 1 year of age be offered food at least once every 12 hours after acceptance for transportation. It is conceivable under these regulations that a nonhuman primate would have been fed up to 24 hours before being consigned for transportation in commerce and would then not be offered food for another 24-hour period. To avoid this occurrence, and to be sure that nonhuman primates are given water as often as required for their well-being, we are proposing to add a certification requirement in proposed § 3.87(d) that would state that each nonhuman primate in a primary enclosure delivered for transport was last offered food during the 12 hours before delivery to a carrier or intermediate handler and was last offered water during the 4 hours before delivery to a carrier or intermediate handler. It must also state the date and time each nonhuman primate in the primary enclosure was last offered food and water. Carriers and intermediate handlers would not be allowed to accept nonhuman primates for transport unless this certification accompanies the animal, is signed and dated by the consignor, and the date and time it was executed is stated. This certification, as well as the others required in proposed § 3.87, would also have to specify the species of nonhuman primate contained in the primary enclosure.

In addition, as provided under proposed § 3.90, "Food and water requirements," the time periods applicable to carriers and intermediate handlers for feeding and watering the nonhuman primates would begin with the time the animal was last offered food and water, in accordance with the certification. The proposed requirement that the consignor certify that the nonhuman primates were provided water within the 4 hours before delivery to the carrier or intermediate handler, and were offered food within 12 hours before delivery to the carrier or intermediate handler accepting the animals, would avoid situations where the carrier or intermediate handler would have to provide food and water immediately upon acceptance. We are adding these requirements so that carriers and intermediate handlers will be better able to provide any needed care and so that the nonhuman primates being transported will not go more than 12 hours without water or 24 hours without being offered food, if they are 1 year of age or more, and will not go more than 12 hours without being offered food, if they are less than 1 year

of age. We believe these timeframes are appropriate for the health and well-being of nonhuman primates.

We would clarify the certifications required from the consignor regarding conformance of the primary enclosure with the regulations in Subpart D and acclimation of a nonhuman primate to temperatures lower than those prescribed in the regulations. We would require that the certification of acclimation be signed by a veterinarian, that it specify a minimum temperature that the nonhuman primate can safely be exposed to, and that it specify each of the animals contained in the primary enclosure to which the certification is attached, rather than referring to the shipment of animals as a whole. The contents of the certifications are provided in subsections (e) and (f) of proposed § 3.87, respectively. We would clarify current § 3.85(c) by requiring that the temperatures to which a nonhuman primate is exposed must not be lower than the minimum temperature specified by the veterinarian and must be reasonably within the generally and professionally accepted range for the nonhuman primate as determined by the veterinarian, considering its age, condition, and species of the animal, even if it is acclimated to temperatures lower than those prescribed in the regulations.

We are proposing to add limitations on how a nonhuman primate can be held at a terminal facility while waiting to be picked up by the consignee. We are proposing to adopt the time limitations provided in Part 2, § 2.80, "C.O.D. shipments". (*See* companion docket no. 88-014, published elsewhere in this issue of the Federal Register.) Accordingly, the consignor must attempt to notify the consignee upon arrival, and at least once every 6 hours for 24 hours after arrival, and then must return the animal to the consignor or to whomever the consignor designates if the consignee cannot be notified. If the consignee is notified and does not take physical delivery of the nonhuman primate within 48 hours of its arrival, the carrier or intermediate handler must likewise return the animal to the consignor or to whomever the consignor designates.

We are proposing to revise current § 3.85(d) to specifically require that carriers and intermediate handlers continue to maintain nonhuman primates in accordance with generally accepted professional and husbandry practices as long as the animals are in their custody and control and until the animals are delivered to the consignee or returned to the consignor or to whomever the consignor designates. We would require the carrier or intermediate handler to obligate the consignor to reimburse it for the expenses incurred by the carrier or intermediate handler in returning the animal. These requirements appear in proposed § 3.87(g).

All of these certifications and notification requirements would help minimize and alleviate many of the stresses of travel for nonhuman primates and are necessary for their general welfare and psychological well-being during travel.

Primary Enclosures Used to Transport Nonhuman Primates

We are proposing to reorganize the provisions of current § 3.86 and to make nonsubstantive changes to this section for clarity. We are proposing the following substantive changes as well.

We are proposing to completely revise the current regulations concerning the number of nonhuman primates that can be transported together in one primary enclosure. The current regulations allow up to ten nonhuman primates to be transported in one primary enclosure. The guidelines issued by the Interagency Primates Steering Committee for the transportation of nonhuman primates state that, as a general principle, nonhuman primates should be transported in individual compartments to avoid transmission of disease except when necessary to minimize social stress. Based upon our experience in regulating the transportation of nonhuman primates and upon consideration of the information available, we have determined that placing this number of nonhuman primates together in a situation that is unusual to and therefore stressful to the animals is dangerous for the animals and to the humans handling them. We are proposing that each nonhuman primate be transported individually in separate primary enclosures that may be connecting, except that the following social groupings may be maintained during transportation: (1) A mother with her nursing infant, (2) an established male-female couple (unless the female is in estrus) or a family group, and (3) a pair of juveniles that have not reached puberty.

The requirements for ventilation openings for primary enclosures that are not permanently affixed to the primary conveyance would be competely revised to provide substantially greater ventilation openings for the nonhuman primates' comfort during travel. The current regulations require that if ventilation openings on two opposite walls of the primary enclosure are present, they comprise at least 16 percent of the surface area of each wall, and if there are ventilation openings on four walls, they comprise at least 8 percent of the surface area of each wall. We are proposing that these requirements be increased to 30 percent and 20 percent, respectively, and that the ventilation openings be located above the midline of the enclosure, since this is safer for the animals and for the humans handling the primary enclosures. The ventilation opening requirements for permanently affixed enclosures that have only one front opening would remain at 90 percent of the surface of the front opening. The proposed revision to the ventilation opening requirements would result in healthier and more comfortable transportation conditions for nonhuman primates, and would therefore promote their psychological well-being.

We are proposing an additional construction requirement that would allow the floor of a primary enclosure to be wire mesh or slatted but it must be designed and constructed so that the nonhuman primate contained inside cannot put any part of its body between the slats or through the mesh in order to prevent injury to the nonhuman primates. Also we would require that primary enclosures be constructed of materials that are nontoxic to the animal and will not otherwise harm their health or well-being.

In proposed § 3.88(f), we are proposing additional marking requirements for the outside of primary enclosures to better ensure that they are handled carefully and in a manner that avoids causing the nonhuman primates additional stress.

We are also proposing that the documents that must accompany the nonhuman primates be held by the operator of the primary conveyance if it is a surface conveyance, or attached to the outside of the primary enclosure. If they are attached to the primary enclosure, they must be placed in a secure but accessible manner so that they can be removed and securely returned, and so that they are easily noticed. We would require that instructions for food and water, and for administration of drugs, medication, and other special care be attached to the primary enclosure. These requirements would help ensure that the animals are treated and handled in accordance with their individual requirements.

Primary Conveyances

Prescribed ambient temperature limits in primary conveyances used to transport nonhuman primates were part of the standards before the 1977

revisions to the regulations, but were inadvertently omitted from those revisions. We are proposing to reinstate them for surface transportation in these proposed regulations in order to prevent nonhuman primates from being transported under intolerable temperature conditions that would be harmful to their health and physical well-being. The current regulations prescribe upper and lower ambient temperature limits for nonhuman primates held in terminal facilities and prescribe lower temperature limits for nonhuman primates placed on transporting devices. It is equally important for the health and well-being of nonhuman primates that these limits be followed while the animals are in transport as well as when they are on either end of their journey. Under our proposed regulations, all persons subject to the Animal Welfare regulations would be required to maintain the temperature inside a primary conveyance between 45 °F (7.2 °C) and 85 °F (30 °C) during surface transportation at all times a nonhuman primate is present. Because it would be impracticable to monitor the ambient air temperature inside the cargo area during air transportation, we would require instead that it be maintained at a level that ensures the health and well-being of the species housed, in accordance with generally accepted professional and husbandry practices, at all times a nonhuman primate is present. We are also proposing to add requirements that a primary enclosure must be positioned in a primary conveyance in a manner that provides protection from the elements, such as rain, wind, snow, and sun, and that is far enough away from animals that are generally considered to be natural predators or enemies of nonhuman primates so that the nonhuman primates cannot reach, see, or smell them. These added precautions would avoid exposing nonhuman primates to known causes of distress and would make traveling less stressful for the animals.

Food and Water Requirements

We are proposing to make nonsubstantive changes to the current regulations to make it clear that carriers and intermediate handlers must provide food and water to nonhuman primates being transported within a prescribed number of hours from the time the animals were last offered food and water. We would require consignors subject to the Animal Welfare regulations to certify the date and time the nonhuman primates were last offered food and water. Carriers and intermediate handlers would be required to determine the appropriate time for providing food and water based upon the information in the certification. Everyone else transporting a nonhuman primate must provide food and water within a prescribed number of hours after they last offered the animal food and water. We are proposing this requirement so that nonhuman primates will not go longer than 24 hours without food or longer than 12 hours without water. The prescribed number of hours differs based upon the age of the nonhuman primate and is the same as in the current regulations. We would also require that nonhuman primates must be offered food within 12 hours before being transported in commerce so that carriers and intermediate handlers would not have to provide food and water immediately upon acceptance. Proper food must be provided, in accordance with § 3.82, however we realize that the necessities of travel may require less variation in the types of food offered and in the method of feeding. Accordingly, footnote 6 of proposed § 3.90 has been added to take the exigencies of travel into account. Requirements for design, construction, and placement of food and water containers would be included for the nonhuman primates' safety, comfort, and well-being. The requirement that carriers and intermediate handlers must not accept nonhuman primates for transport unless written instructions concerning food and water requirements are affixed to the outside of the primary enclosure has been incorporated in proposed § 3.87, as previously discussed. Proposed § 3.90 would require consignors subject to the Animal Welfare regulations to attach securely to the primary enclosure all written instructions concerning the nonhuman primates' food and water requirements during transportation.

Care in Transit

We would clarify current § 3.89 to expressly require compliance with these regulations by any person subject to the Animal Welfare regulations who is transporting a nonhuman primate in commerce, regardless of whether the nonhuman primate is consigned for transport.

We are proposing nonsubstantive changes to this section for purposes of clarity along with the following substantive changes.

We are proposing to require that during surface transportation, regulated persons subject to the regulations must obtain any veterinary care needed for the nonhuman primate at the closest available veterinary facility. During air transportation, carriers or intermediate handlers must arrange for any veterinary care that is needed for the nonhuman primate as soon as possible.

We are also proposing to add an exemption to the current regulations that prohibit the transportation in commerce of a nonhuman primate in obvious physical distress that would allow transport for the purpose of providing veterinary care for the condition.

When nonhuman primates are initially removed from their primary enclosures after travel they may be unusually active or perhaps agitated. In order to avoid any resultant injury to the animals we are proposing a requirement that would allow only authorized and experienced persons to remove nonhuman primates from their primary enclosures during transport in order to protect both the nonhuman primates, which could injure themselves in frenzied movement, and the people handling them.

We are proposing to add a subsection that would specify that these transportation standards remain in effect and must continue to be complied with until the animal reaches its final destination, or until the consignee takes physical delivery of the animal if the animal has been consigned for transportation. We believe that this provision is necessary to prevent any gap in care for the nonhuman primate and in responsibility for its care.

Terminal Facilities

Current § 3.90 imposes duties on carriers and intermediate handlers holding nonhuman primates in animal holding areas of terminals to keep the animals away from inanimate cargo, to clean and sanitize the area, to have an effective pest control program, to provide ventilation, and to maintain the ambient temperature within certain prescribed limits. Under the current regulations, there is no similar obligation imposed upon other persons who transport these animals. As a result, animals could be held in animal holding areas under hazardous conditions.

We are proposing that the same duties currently imposed upon carriers and intermediate handlers be imposed upon any person subject to the Animal Welfare regulations transporting nonhuman primates and holding them in animal holding areas, since the animals require the same minimum level of care regardless of which regulated persons is transporting the animals.

We would add restrictions to prevent regulated persons from holding nonhuman primates within physical and

visual reach of other animals and other species of nonhuman primates, since this is upsetting to them. We are also proposing that the length of time regulated persons be allowed to hold nonhuman primates in terminal facilities upon arrival be the same as that allowed for consigned animals under proposed § 3.87(g). We believe that this limitation on holding periods in terminal facilities is necessary to prevent regulated persons from leaving nonhuman primates in terminal facilities for any reason, such as to await additional shipments, and that it will help reduce the stress of travel for nonhuman primates.

Proposed § 3.92 would continue the temperature and ventilation requirements contained in current § 3.90 and would also contain the provisions requiring shelter from the elements for nonhuman primates that are currently in § 3.91 "Handling," because they are applicable to regulated persons holding nonhuman primates in animal holding areas of terminal facilities. The proposed regulations for handling would be limited to the safeguards that must be provided during physical handling and movement of nonhuman primates, as its heading suggests.

Handling

Current § 3.91 imposes duties on carriers and intermediate handlers for proper handling and movement of nonhuman primates. For the reasons explained above under "Terminal facilities," we are proposing that these same duties be imposed upon any person subject to the Animal Welfare regulations handling a nonhuman primate at any time during the course of transportation in commerce, so that the animals' health, safety, and well-being will be protected at all times during transport. The proposed regulations would continue to include movement from an animal holding area of a terminal facility to a primary conveyance and from a primary conveyance to a terminal facility. It would also continue to provide requirements for movement of a nonhuman primate on a transporting device. We are proposing to broaden this section to include movement within and between primary conveyances, and movement within and between terminal facilities, because nonhuman primates may travel on several different primary conveyances and be moved around within terminal complexes in the course of their travel.

We are also proposing to require that transporting devices on which nonhuman primates are placed to move them must be covered to protect the nonhuman primates when the outdoor temperature falls below 45 ° (7.2 °C). The current regulations require this protection when the outdoor temperature falls below 50 °(10 °C). We believe that providing this protection becomes necessary at the lower temperature proposed, and that the proposed requirement will protect the health and well-being of nonhuman primates.

Air carriers commonly use conveyor belts and inclined belts for loading and unloading animals into airplane cargo space. These methods of loading can cause psychological distress to the animals. We are proposing to allow nonhuman primates to be placed on inclined conveyor belts used for loading and unloading aircraft only, if an attendant is present at each end of the conveyor belt in case an animal has an extreme adverse reaction. We are proposing to prohibit placing nonhuman primates on unattended conveyor belts or on elevated conveyor belts, such as baggage claim conveyor belts, since these forms of tilted movement cause nonhuman primates extreme distress and alternative means of moving the animals can generally be provided without great inconvenience.

Statutory Authority for This Proposed Rule

This proposed rule is issued pursuant to the Animal Welfare Act (Act), as amended, 7 U.S.C. 2131–2157. Congress, in enacting the Food Security Act of 1985, Pub. L. No. 99–198, added significantly to the Secretary's existing responsibilities to promulgate standards for the care and treatment of animals covered under the Act. The declared policy of the Act is to ensure that animals intended for use in research facilities, as pets, or for exhibition purposes, are provided humane care and treatment; to assure the humane treatment of animals during transportation; and to prevent the sale of stolen animals.

The Act requires that the Secretary of Agriculture promulgate standards to govern the humane handling, care, treatment and transportation of animals by dealers, research facilities, and exhibitors. These standards are to include minimum requirements for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperatures, adequate veterinary care, and separation of species. The 1985 amendments to the Act specifically require the Secretary to promulgate standards for exercise of dogs and for a physical environment adequate to promote the psychological well-being of primates.

The proposed rule includes changes and additions to the standards required by the 1985 amendments as well as modifications based on the Department's experience in administering and enforcing the Act. The Act authorizes these changes specifically in section 13 (7 U.S.C. 2143) and in the grant of rulemaking authority contained in section 21 (7 U.S.C. 2151).

Executive Order 12291

This proposed action has been reviewed pursuant to the requirements of Executive Order 12291 and it has been determined that it will have an impact in excess of $100 million annually on the regulated industries and the general economy. The Administrator has therefore determined that it would be a "major rule." Some of the major costs to the regulated industries in complying with the proposed regulations would result from: (1) Renovating, equipping, replacing, or constructing animal housing facilities; (2) the exercise for dog requirements; and (3) the psychological well-being of nonhuman primates.

The economic impacts of this rule are discussed in more detail in a Regulatory Impact Analysis, which is available for public inspection in Room 1141 of the South Building, U.S. Department of Agriculture between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays (address above). Main findings of this analysis are summarized below.

SUMMARY OF REGULATORY IMPACT ANALYSIS

Costs	Benefits
Direct	Direct
Regulated industry.....	Increased public satisfaction from improved animal welfare.*
Capital expenses:	
(all parts) $876 million.....	Improved research information.*
(parts 1–2) $142 million	Productivity gains for regulated industries.*
Annual costs:	
(all parts) $207 million.....	
(parts 1–2) $126 million	
APHIS program costs impact on federal sites* $2 million.	
Indirect	Indirect
Opportunity costs for users of biomedical research (goods and services), pet industry, and animal exhibits*.	Market effects for suppliers of animal husbandry products.*

SUMMARY OF REGULATORY IMPACT ANALYSIS—Continued

Costs	Benefits
Increased federal financial support for biomedical community.* Non-market effects*	Non-market effects.*

*Not quantified.

Compliance with more stringent federal regulations on the humane care and treatment of animals used for research, testing, teaching, exhibition, and business ventures would result in major direct and indirect effects imposed on the regulated industry and the general economy. An examination of the estimated cost impacts indicates that the amended regulations constitute a "major rule" based on annual effects in excess of $100 million on the economy and large cost increases on regulated industries for animal uses and maintenance, in particular to the biomedical research community. However, this study could not properly assess the relative significance of these cost increases on the regulated industry or the presence of adverse effects on competition, innovation, and the ability of domestic enterprises to compete with foreign enterprises in international markets.

Regulated persons or establishments will be required to spend approximately $876 million in capital expenditures over the next two or three years. Of this amount approximately 16 percent is attributable to Parts 1 and 2. If Parts 1 and 2 were enforced separately, regulated research facilities will be required to spend approximately $142 million to renovate, equip, replace, or construct aseptic surgical facilities, and provide for adequate pre- and post-surgical care. Capital expenditures attributable to Part 3 include costs for renovation, equipment replacement, and new construction of animal housing facility space. Capital expenditures to improve animal housing facilities would result from the new minimum standards for general environmental conditions, space or primary enclosure size requirements, exercise of dogs, and enrichment of nonhuman primate enclosures.

In addition to capital expenditures, total annual operating expenditures estimated at $207 million will also be required. Approximately 60 percent of this total ($126 million) is accounted for by Parts 1 and 2, primarily the requirements for the establishment and operations of the institutional animal care and use committees, additional responsibilities for attending veterinarians, and record-keeping requirements. Annual expenditures attributable to Part 3 would result from the need for additional personnel (animal handlers) to exercise dogs, and the daily maintenance of animal housing facilities.

An important result of this regulatory analysis is that policy decisions must consider other direct and indirect effects associated with the promulgation and enforcement of federal rules. Increased federal legislation causes important economic benefits and costs which are unevenly distributed among registrants and licensees. Direct benefits accrue to society by knowing that animals may be better cared for and treated humanely. The value of these social benefits are subject to personal preferences and concerns. Improvements in the well-being of regulated animals may also provide gains in productivity to the industry. On the other hand, increased costs of compliance will be passed from the regulated industry to consumers who purchase their goods and services. For example, the field of biomedical research and education depends heavily on the use of animals to conduct tests and experiments. Increased costs for animal uses have broader economic and health implications for all of us. Study results do not suggest that these regulations would cause establishments to abandon the use of animals since current biomedical research outlays are in excess of $12.8 billion per year. Nonetheless, there could be important effects associated with allocating additional funds or expenditures to comply with the amended Animal Welfare regulations.

The Department will collect additional data and refine the analysis with regard to the proposed amendments to Part 3. The results will be available upon publication on the final rulemaking for Part 3. It is not expected that the revised analysis will affect the determination that this rule would have an impact in excess of $100 million annually.

Regulatory Flexibility Act

As part of the regulatory impact analysis performed by the Department in amending the Animal Welfare regulations, we have analyzed the potential impact on small entities of the proposed amendments to Part 3, as required by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Based upon this analysis, the Administrator has determined that the proposed amendments to Part 3, if implemented, would have a significant economic impact on a substantial number of small entities.

The economic impacts of this proposed rule on small entities are discussed in greater detail in the Regulatory Flexibility Analysis, which is available for public inspection in Room 1141 of the South Building, U.S. Department of Agriculture between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

The principal findings of the analysis are summarized below.

Study results indicate that APHIS Animal Welfare regulations would place a significant burden on a substantial number of small licensees that breed, deal or exhibit regulated animals. Total capital expenditures required in the next two or three years are estimated to be approximately $93.9 million. These will affect 2,155 small breeders (77 percent of small licensed breeders), 371 small dealers (37 percent of small dealers) and 1,245 small exhibitors (92 percent of small exhibitors). The expected increase in variable operating costs is $6.8 million. Annual operating expenditures are significantly lower than the estimated capital expenditrues, however, these would affect all small licensees. In comparison to reported annual gross income estimates of $8.6 million for all small breeders and $0.8 million for all small dealers, the added expenditures represent significant impacts.

Of the small licensees, breeders will be most affected. Breeders represent about 57 percent of the small licensees and will incur approximately 66 percent of the total capital and variable cost impacts. An important distributional effect of the regulations is that the impact on breeders will be concentrated in the Central region. Eighty-five percent of small breeders, mainly dog breeders, are located in this region.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with state and local officials. (See 7 CFR 3015, Subpart V.)

Paperwork Reduction Act

In accordance with section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the information collection provisions that are included in this proposed rule will be submitted for approval to the Office of Management and Budget (OMB). Your written comments will be considered if you submit them to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. You should submit a duplicate copy of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 866, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

List of Subjects in 9 CFR Part 3

Animal welfare, Humane animal handling, Pets, Transportation.

Accordingly, we propose to amend Part 3 as follows:

PART 3—STANDARDS

1. The authority citation for Part 3 would be revised to read as follows, and the authority citation following all the sections would be removed.

Authority: 7 U.S.C. 2131–2156; 7 CFR 2.17, 2.51, and 371.2(d).

2. The table of contents for Subpart A consisting of §§ 3.1 through 3.19, would be revised to read as follows:

Subpart A—Specifications for the Humane Handling, Care, Treatment, and Transportation of Dogs and Cats

Facilities and Operating Standards

Subpart A—Specifications for the Humane Handling, Care, Treatment, and Transportation of Dogs and Cats [1]

Facilities and Operating Standards

§ 3.1 Housing facilities, general.

(a) *Structure; construction.* Housing facilities for dogs and cats must be designed and constructed so that they are structurally sound. They must be kept in good repair, and they must protect the animals from injury, contain the animals securely, and restrict other animals and unauthorized humans from entering.

(b) *Condition and site.* Housing facilities and areas used for storing animal food or bedding must be free of any accumulation of trash, waste material, junk, weeds, and other discarded materials. Animal areas inside of housing facilities must be kept neat and free of clutter, including equipment, furniture, and stored material, but may contain materials actually used and necessary for cleaning the area, such as brooms, mops, mop buckets, trash containers, and fixtures necessary for proper husbandry practices, such as tables, cabinets, and sinks. Housing facilities other than those maintained by research facilities and federal research facilities must be physically separated from any other business. If a housing facility is located on the same premises as another business, it must be physically separated from the other business so that unauthorized humans, and animals the size of dogs, skunks, and raccoons are prevented from entering it.

(c) *Surfaces.*—(1) *General requirements.* The surfaces of housing facilities—including houses, dens, and other furniture-type fixtures and objects within the facility—must be constructed in a manner and made of materials that allow them to be readily cleaned and sanitized, or removed or replaced when worn or soiled. Interior surfaces and any surfaces that come in contact with dogs or cats must:

(i) Be free of rust that prevents the required cleaning and sanitization, or that affects the structural strength of the surface; and

(ii) Be free of jagged edges or sharp points that might injure the animals.

(2) *Maintenance and replacement of surfaces.* All surfaces must be maintained on a regular basis. Surfaces of housing facilities—including houses, dens, and other furniture-type fixtures and objects within the facility—that cannot be readily cleaned and sanitized, must be replaced when worn or soiled.

(3) *Cleaning.* Hard surfaces with which the dogs or cats come in contact must be cleaned daily and sanitized at least once every two weeks, and as often as necessary to prevent any accumulation of excreta and disease hazards. Floors made of dirt, sand, gravel, grass, or other similar material must be raked and spot-cleaned daily, and the contaminated material must be replaced whenever this raking and spot-cleaning is not sufficient to prevent or eliminate odors, diseases, insects, pests, or vermin infestation. All other surfaces of housing facilities must be cleaned daily and sanitized when necessary to satisfy generally accepted husbandry standards and practices. Sanitization may be done using any of the methods provided in § 3.10(b)(3) for primary enclosures.

(d) *Water and electric power.* The housing facility must have reliable electric power adequate for heating, cooling, ventilation, and lighting, and for carrying out other husbandry requirements in accordance with the regulations in this subject. The housing facility must provide adequate mechanically pressurized running potable water for the dogs' and cats' drinking needs, for cleaning, and for carrying out other husbandry requirements.

(e) *Storage.* Supplies of food and bedding must be stored in leakproof containers that protect the supplies from spoilage, contamination, and vermin infestation. The supplies must be stored off the floor and away from the walls, to allow cleaning underneath and around the supplies. Perishable food must be refrigerated, and all food must be stored in a manner that prevents contamination and deterioration of its nutritive value. All open supplies of food and bedding must be kept in leakproof containers with tightly fitting lids to prevent contamination and spoilage. Only food and bedding that is currently being used may be kept in the animal areas. Substances that are toxic to the dogs and cats must not be stored in animal areas or in food storage and preparation areas.

(f) *Drainage and waste disposal.* Housing facility operators must provide daily (or more often as necessary) removal and disposal of animal and food wastes, bedding, debris, garbage, water, other fluids and wastes, and dead animals. Housing facilities must be equipped with disposal facilities and drainage systems that are constructed and operated so that animal waste and water are rapidly eliminated and animals stay dry. Disposal and drainage systems must minimize vermin and pest infestation, insects, odors, and disease hazards. All drains must be properly constructed, installed, and maintained. If closed drainage systems are used, they must be equipped with traps and prevent the backflow of gases and the backup of sewage onto the floor. If the facility uses sump or settlement ponds, or other similar systems for drainage and animal waste disposal, the system must be located far enough away from the animal area of the housing facility to prevent odors, diseases, pests, and vermin infestation. Puddles of water in animal areas must be promptly mopped up or drained so that the animals stay dry. Trash containers in housing facilities and in food storage and food

[1] These minimum standards apply only to live dogs and cats, unless stated otherwise.

preparation areas must be leakproof and must have tightly fitted lids on them at all times. Dead animals, animal parts, and animal waste must not be kept in food storage or food preparation areas, food freezers, food refrigerators, or animal areas.

(g) *Washrooms and sinks.* Washing facilities such as washrooms, basins, sinks, or showers must be provided for animal caretakers and must be readily accessible.

§ 3.2 Indoor housing facilities.

(a) *Heating, cooling, and temperature.* Indoor housing facilities for dogs and cats must be sufficiently heated and cooled when necessary to protect the dogs and cats from cold and hot temperatures and to provide for their health, and well-being. When dogs or cats are present, the ambient temperature in the facility must not fall below 50 °F (10 °C) for dogs and cats not acclimated to lower temperatures, for those breeds that cannot tolerate lower temperatures without stress or discomfort (such as short-haired breeds), and for sick, aged, young, or infirm dogs and cats. The ambient temperature must not fall below 45 °F (7.2 °C) at any time, and must not rise above 95 °F (35 °C).

(b) *Ventilation.* Indoor housing facilities for dogs and cats must be sufficiently ventilated at all times when dogs and cats are present to provide for their health, comfort, and well-being, and to minimize odors, drafts, ammonia levels, and moisture condensation. Air, preferably fresh air, must be provided by windows, vents, fans, or air-conditioning. Auxiliary ventilation or air-conditioning must be provided when the ambient temperature is 85 °F (29.5 °C) or higher. The relative humidity must be between 30 and 70 percent.

(c) *Lighting.* Indoor housing facilities for dogs and cats must be lighted well enough to permit routine inspection and cleaning of the facility, and observation of the dogs and cats. Animal areas must be lighted for at least 8 hours a day, by either natural or artificial light, corresponding to the natural period of daylight. If only artificial light, such as fluorescent light, is provided, it must provide full-spectrum illumination. Primary enclosures must be placed so as to protect the dogs and cats from excessive light.

(d) *Interior surfaces.* The floors and walls of indoor housing facilities, and any other surfaces in contact with the animals, must be impervious to moisture. The ceilings of indoor housing facilities must be impervious to moisture, or be replaceable. An example of this would be a suspended ceiling with replaceable panels.

§ 3.3 Sheltered housing facilities.

(a) *Heating, cooling, and temperature.* The sheltered part of sheltered housing facilities for dogs and cats must be sufficiently heated and cooled to protect the dogs and cats from cold and hot temperatures and to provide for their health, comfort, and well-being. The ambient temperature in the sheltered part of the facility must not fall below 50 °F (10 °C) for dogs and cats not acclimated to lower temperatures, for those breeds that cannot tolerate lower temperatures without stress and discomfort (such as short-haired breeds), and for sick, aged, young, or infirm dogs or cats. The ambient temperature must not fall below 35 °F (1.7 °C) at any time, and must not rise above 95 °F (35 °C).

(b) *Ventilation.* The enclosed or sheltered part of sheltered housing facilities for dogs and cats must be sufficiently ventilated when dogs or cats are present to provide for their health, comfort, and well-being, and to minimize odors, draft, ammonia levels, and moisture condensation. Air, preferably fresh air, must be provided by windows, doors, vents, fans, or air-conditioning. Auxiliary ventilation, such as exhaust fans or air-conditioning, must be provided when the ambient temperature is 85 °F (29.5 °C) or higher.

(c) *Lighting.* Sheltered housing facilities for dogs and cats must be lighted well enough to permit routine inspection and cleaning of the facility, and observation of the dogs and cats. Animal areas must be lighted for at least 8 hours a day by either natural or artificial light. Primary enclosures must be placed so as to protect the dogs and cats from excessive light.

(d) *Shelter from the elements.* Dogs and cats must be provided with adequate shelter from the elements at all times.

(e) *Surfaces.* (1) The following areas in sheltered housing facilities must be impervious to moisture:

(i) Indoor floor areas in contact with the animals;

(ii) Outdoor floor areas in contact with the animals, when the floor areas are not exposed to the direct sun, or are made of a hard material such as wire, wood, metal, or concrete; and

(iii) All walls, boxes, houses, dens, and other surfaces in contact with the animals.

(2) Outside floor areas in contact with the animals and exposed to the direct sun may consist of compacted earth, sand, gravel, or grass.

§ 3.4 Outdoor housing facilities.

(a) *Restrictions.* (1) The following categories of dogs or cats must not be kept in outdoor facilities:

(i) Dogs or cats that are not acclimated to the temperatures prevalent in the area or region where they are maintained;

(ii) Breeds of dogs or cats that cannot tolerate the prevalent temperatures of the area without stress or discomfort (such as short-haired breeds in cold climates); and

(iii) Sick, infirm, aged or young dogs or cats.

(2) When their acclimation status is unknown, dogs and cats must not be kept in outdoor facilities during any month in which, during the preceding 5 years, the temperature at the facility's location has been less than 35 °F (1.7 °C).

(b) *Capacity.* Outdoor facilities for dogs or cats must include a shelter structure that is accessible to all the animals in each outdoor facility, and that is large enough to allow all animals in the shelter structure to sit, stand, and lie in a normal manner, and to turn about freely. In addition to the shelter structure, a separate outside area of shade must be provided, large enough to contain all the animals at one time and protect them from the direct rays of the sun.

(c) *Construction.* Building surfaces in contact with animals in outdoor housing facilities must be impervious to moisture. Metal barrels, old refrigerators or freezers, and the like must not be used as shelter structures. The floors of outdoor housing facilities may be of compacted earth, sand, gravel, or grass, and must be replaced if there are any prevalent odors, diseases, insects, pests, or vermin.

(d) *Shelter from the elements.* Shelters in outdoor facilities for dogs or cats must:

(1) Provide the dogs and cats with adequate protection and shelter from the cold and heat;

(2) Provide the dogs and cats with protection from the direct rays of the sun and the direct effect of wind, rain, or snow;

(3) Be provided with a wind break and rain break at the entrance; and

(4) Contain clean, dry, bedding material.

§ 3.5 Mobile or traveling housing facilities.

(a) *Heating, cooling, and temperature.* Mobile or traveling housing facilities for dogs and cats must be sufficiently heated and cooled when necessary to protect the dogs and cats from cold and hot temperatures and to provide for their

health, comfort, and well-being. The ambient temperature in the mobile or traveling housing facility must not fall below 50 °F (10 °C) for dogs and cats not acclimated to lower temperatures, for those breeds that cannot tolerate lower temperatures without stress or discomfort (such as short-haired breeds), and for sick, aged, young, or infirm dogs and cats. The ambient temperature must not fall below 35 °F (1.7 °C) at any time, and must not exceed 95 °F (35 °C) for all dogs and cats.

(b) *Ventilation.* Mobile or traveling housing facilities for dogs and cats must be sufficiently ventilated at all times when dogs or cats are present to provide for the health, comfort, and well-being of the animals, and to minimize odors, drafts, ammonia levels, moisture condensation, and exhaust fumes. Air, preferably fresh air, must be provided by means of windows, doors, vents, fans or air-conditioning. Auxiliary ventilation, such as fans, blowers, or air-conditioning, must be provided when the ambient temperature within the animal housing area is 85 °F (29 °C) or higher.

(c) *Lighting.* Mobile or traveling housing facilities for dogs and cats must be lighted well enough to permit proper cleaning and inspection of the facility, and observation of the dogs and cats. Animal areas must be lighted for at least 8 hours each day, corresponding to the natural period of daylight. If only artificial light, such as fluorescent light, is provided, it must provide full-spectrum illumination.

§ 3.6 Primary enclosures.

Primary enclosures for dogs and cats must meet the following minimum requirements:

(a) *General requirements.* (1) Primary enclosures must be designed and constructed of suitable materials so that they are structurally sound. The primary enclosures must be kept in good repair.

(2) Primary enclosures must be constructed and maintained so that they:

(i) Have no sharp points or edges that could injure the dogs and cats;

(ii) Protect the dogs and cats from injury;

(iii) Contain the dogs and cats securely;

(iv) Keep predators and unauthorized individuals from entering the enclosure;

(v) Enable the dogs and cats to remain dry and clean;

(vi) Provide shelter and protection from extreme temperatures and weather conditions that may be uncomfortable or hazardous to the dogs and cats;

(vii) Provide sufficient shade to shelter all the dogs and cats housed in the primary enclosure at one time;

(viii) Provide the dogs and cats with easy and convenient access to clean food and water;

(ix) Enable all surfaces in contact with the dogs and cats to be readily cleaned and sanitized in accordance with § 3.10(b) of this subpart, or be replaceable when worn or soiled;

(x) Have floors that are constructed in a manner that protects the dogs' and cats' appendages from injury, and that, if of mesh or slatted construction, do not allow the dogs' and cats' appendages to pass through any openings in the floor; and

(xi) Provide sufficient space to allow each dog and cat to turn about freely, to stand, sit, and lie in a comfortable, normal position, and to walk in a normal manner.

(b) *Additional requirements for cats*— (1) *Space.* Each cat, including weaned kittens, that is housed in any primary enclosure must be provided minimum vertical space and floor space as follows:

(i) Each primary enclosure housing cats must be at least 24 in. high (60.96 cm);

(ii) Cats up to and including 8.8 lbs (4 kg) must be provided with at least 3.0 ft^2 (0.28 m^2);

(iii) Cats over 8.8 lbs (4 kg) must be provided with at least 4.0 ft^2 (0.37 m^2);

(iv) Each queen with nursing kittens must be provided with an additional amount of floor space, equivalent to at least 5 percent of her minimum required floor space for each nursing kitten in the litter (e.g., five nursing kittens require a 25-percent increase and 10 nursing kittens require a 50-percent increase); and

(v) The minimum floor space required by this paragraph is exclusive of any food or water pans.

(2) *Compatibility.* All cats housed in the same primary enclosure must be compatible, as determined by observation. Not more than 12 adult nonconditioned cats may be housed in the same primary enclosure. Queens in heat may not be housed in the same primary enclosure with sexually mature males, except for breeding. Except when maintained in breeding colonies, queens with litters may not be housed in the same primary enclosure with other adult cats, and kittens under 4 months of age may not be housed in the same primary enclosure with adult cats. Cats with a vicious or aggressive disposition must be housed separately.

(3) *Litter.* In all primary enclosures having a solid floor, a receptacle containing sufficient clean litter must be provided to contain excreta and body wastes.

(4) *Resting surfaces.* Each primary enclosure housing cats must contain a solid resting surface or surfaces that, in the aggregate, are large enough to hold all the occupants of the primary enclosure at the same time comfortably. The resting surfaces must be elevated, impervious to moisture, and be able to be easily cleaned and sanitized, or easily replaced when soiled or worn. The resting surfaces are not considered part of the minimum floor space.

(5) *Cats in mobile or traveling shows or acts.* Cats that are part of a mobile or traveling show or act may be kept, while the show or act is traveling from one temporary location to another, in transport containers that comply with all requirements of § 3.14 of this subpart other than the marking requirements in § 3.14(a)(6) of this subpart. When the show or act is not traveling, the cats must be placed in primary enclosures that meet the minimum requirements of this section.

(c) *Additional requirements for dogs*— (1) *Space.* (i) Each dog housed in a primary enclosure (including weaned puppies) must be provided a minimum amount of floor space calculated as follows: find the mathematical square of the sum of the length of the dog in inches (measured from the tip of its nose to the base of its tail) plus 6 inches; then divide the product by 144. The calculation is: (length of dog in inches+6)×(length of dog in inches+6)=required floor space in square inches. Required floor space in inches/144=required floor space in square feet.

(ii) Each bitch with nursing puppies must be provided with an additional amount of floor space, equivalent to at least 5 percent of her minimum required floor space for each nursing puppy in the litter (e.g., five nursing puppies require a 25-percent increase and 10 nursing puppies require a 50-percent increase).

(iii) The interior height of a primary enclosure must be at least 6 inches higher than the highest point of the body (normally the ears) of the tallest dog in the enclosure when it is in a normal standing position.

(2) *Dogs on tethers.* Dogs may be kept on tethers only in outside housing facilities that meet the requirements of § 3.4 of this subpart, and only when the tether meets the requirements of this paragraph. The tether must be attached to the front of the dog's shelter structure or to a post in front of the shelter structure and must be at least three times the length of the dog, as measured from the tip of its nose to the base of its

tail. The tether must allow the dog convenient access to the shelter structure and to food and water containers. The tether must be of the type and strength commonly used for the size dog involved and must be attached to the dog by a well-fitted collar that will not cause trauma or injury to the dog. Collars made of materials such as wire, flat chains, chains with sharp edges, or chains with rusty or nonuniform links are prohibited. The tether must be attached so that the dog cannot become entangled with other objects or come into physical contact with other dogs in the outside housing facility, and so the dog can roam to the full range of the tether. Dog housing areas where dogs are on tethers must be enclosed by a perimeter fence that is at least 6 feet high and that protects the dogs from other animals, contains them if they should free themselves of the tether, and prevents dogs, raccoons, skunks, and animals of similar size from going through it or under it.

(3) *Compatibility.* All dogs housed in the same primary enclosure must be compatible, as determined by observation. Not more than 12 adult nonconditioned dogs may be housed in the same primary enclosure. Bitches in heat may not be housed in the same primary enclosure with sexually mature males, except for breeding. Except when maintained in breeding colonies, bitches with litters may not be housed in the same primary enclosure with other adult dogs, and puppies under 4 months of age may not be housed in the same primary enclosure with adult dogs. Dogs with a vicious or aggressive disposition must be housed separately.

(4) *Dogs in mobile or traveling shows or acts.* Dogs that are part of a mobile or traveling show or act may be kept, while the show or act is traveling from one temporary location to another, in transport containers that comply with all requirements of § 3.14 of this subpart other than the marking requirements in § 3.14(a)(6) of this subpart. When the show or act is not traveling, the dogs must be placed in primary enclosures that meet the minimum requirements of this section.

(d) *Variance from minimum space requirements*—(1) *Definition.* For the purposes of this subpart, a "variance" means the written permission from the Administrator that is required to operate as a licensee or registrant under the Animal Welfare Act without fully complying with the minimum space requirements provided in this subpart. A variance may be limited in scope both as to time and to the primary enclosures covered by it, and will specify the portions of a registrant's or licensee's facilities covered by the variance.

(2) *Who may apply; eligibility.* Registrants and licensees that maintain or handle dogs or cats, or that have dogs or cats on the premises or under their control or supervision, and that do not comply with one or more of the minimum space requirements provided in this subpart may apply to the Administrator for a variance. Any housing facilities under construction or in the design and preliminary construction stages on the effective date of these regulations are not eligible for a variance, unless the registrant or licensee demonstrates to the Administrator that construction is no nearly complete that a variance is necessary for the registrant or licensee to comply with the minimum space requirements.

(3) *When to apply.* Eligible registrants and licensees requiring a variance in accordance with paragraph (d)(2) of this section must apply to the Administrator within 60 days of the effective date of these regulations.

(4) *Application.* An application for a variance must be in writing and must list in detail each of the minimum space requirements that cannot be complied with, the amount of time necessary for the applicant to come into compliance with the minimum space requirements, the specific reasons why the variance is being requested, the species and number of dogs and cats that will be affected by the variance, and the estimated cost of compliance. A statement from the attending veterinarian concerning the age and health status of the dogs and cats affected by the variance and addressing whether the granting of a variance would be detrimental to the affected dogs and cats must accompany the application. The Administrator may grant the application if he or she determines that it is justified or deny it it he or she determines that it is not justified under the circumstances, or that granting it would be detrimental to the health and well-being of the dogs and cats affected by the variance. The grant or denial will be in writing. The Administrator may require a report to be submitted by an outside expert to help determine whether a variance would be detrimental to the health and well-being of the dogs and cats affected. The cost of the report must be paid by the applicant. The applicant may request that the Administrator reconsider his or her decision to deny an application by writing to the Administrator within ten (10) days after the applicant has received the denial. The applicant must explain, in writing, why he or she believes the variance should have been granted. The Administrator will notify the applicant in writing of the final decision as promptly as circumstances allow.

(5) *Duration and extension.* An initial variance may be granted, at the sole discretion of the Administrator, for the period of time the Administrator determines is necessary for the applicant to comply with the minimum space requirements, based upon the facts presented in the application, up to a maximum time of 2 years. The Administrator may grant a single extension of up to 1 year upon written request if the Administrator determines that it is justified due to unforeseen situations that prevent the registrant or licensee from fully complying during the initial variance period. A written request for an extension must be received by the Administrator at least 60 days before the expiration date of the initial variance. No more than one extension will be granted. The applicant may request that the Administrator reconsider his or her decision to deny an application for extension by writing to the Administrator within ten (10) days after the applicant has received the denial. The applicant must explain, in writing, why he or she believes the extension should have been granted. The Administrator will notify the applicant in writing of the final decision as promptly as circumstances allow. Until a final determination is made, the extention will not be in effect. If the extension is granted on reconsideration, it will be retroactive to the termination date of the initial variance.

(6) *Revocation.* A variance may be revoked by the Administrator at any time if he or she determines that it was obtained in bad faith, that the purpose for which the variance was granted is not being carried out, or that it is detrimental to the health and well-being of the dogs or cats affected. Revocation of a variance will be in writing and will be effective upon receipt.

Animal Health and Husbandry Standards

§ 3.7 Exercise and socialization for dogs.

(a) Social contact while being housed, held, or maintained. (1) All dogs housed, held, or maintained by any dealer, exhibitor, or research facility including federal research facilities, must be maintained in compatible groups *unless*:

(i) Housing in compatible groups is not in accordance with an animal care and use procedure, and the animal care and use procedure has been approved by the research facility's Committee;

(ii) In the opinion of the attending veterinarian such housing would adversely affect the health or well-being of the dog(s); or

(iii) Any dog exhibits aggressive or vicious behavior.

(2) All dogs housed, held, or maintained by any dealer, exhibitor, or research facility, including federal research facilities, must be able to hear and see other dogs *unless*:

(i) Such contact is not in accordance with an animal care and use procedure, and the animal care and use procedure has been approved by the research facility's Committee;

(ii) In the opinion of the attending veterinarian, such contact would adversely affect the health or well-being of the dog(s); or

(iii) Only one dog is housed, held, or maintained by the dealer, exhibitor, or research facility. In such instances, the single dog must receive positive physical contact with humans at least once a day. The positive physical contact with humans must total at least 60 minutes each day and may be given in one or more periods.

(b) Release for exercise and socialization—(1) Dogs housed individually. (i) Dogs housed, held, or maintained by any dealer, exhibitor, or research facility, including federal research facilities, must be released at least once a day for exercise and socialization if they are:

(A) Kept individually in cages; or

(B) Kept individually in pens or runs that provide less than four times the floor space required for that dog by § 3.6(c)(1) of this subpart, and that do not allow visual and physical contact with neighboring dogs (for example, concrete block pens and runs).

(ii) The exercise area must be the larger of 80 square feet or twice the minimum floor space required by § 3.6(c)(1) of this subpart. However, dogs whose release for exercise and socialization is prohibited by an animal care and use procedure approved by the Committee are not subject to the 80-square-feet-minimum provision of this paragraph, but must be maintained in pens or runs that provide each dog with at least twice the minimum floor space required by § 3.6(c)(1) of this subpart.

(iii) Dogs housed, held, or maintained by any dealer, exhibitor, or research facility do not need to be released each day for exercise and socialization if they are kept in pens or runs that:

(A) Provide at least four times the required space for that dog; and

(B) Allow visual and physical contact with neighboring dogs.

(2) Dogs housed, held, or maintained in groups by any dealer, exhibitor, or research facility, including a federal research facility, must be released at least once a day for exercise and socialization, unless the dogs are maintained in pens or runs that provide the greater of 80 square feet or 150 percent of the space each dog would require if maintained separately under the minimum floor space requirements of § 3.6(c)(1) of this subpart. If a run or open area is used for exercise for dogs housed in groups, it must be the greater of 80 square feet or 150 percent of the minimum space requirement for each dog in the exercise area. (For example, a 28-inch beagle requires a minimum floor space of 8 square feet. Therefore, for six beagles housed together, 150 percent of six times the minimum per-beagle requirement of 8 square feet is 72 square feet. This is less than 80 square feet. Therefore, the larger floor space, 80 square feet, would be required.)

(3) Exercise periods must total at least 30 minutes each day and may be given in one or more release periods.

(c) Methods of exercise.

(1) The attending veterinarian must determine the type of exercise to be used. The exercise may be provided by:

(i) Walking on a leash;

(ii) Releasing the dog(s) into an open area;

(iii) Providing access to a run; or

(iv) Some other similar arrangement.

(2) Forced exercise methods or devices such as swimming, treadmills, or carousel type device do not meet the exercise requirements of this section.

(d) Documentation of the release of each dog for exercise must be kept by the registrant or licensee, and is subject to APHIS inspection.

(e) Exemptions. The attending veterinarian may exempt a particular dog from the exercise release period required for it under paragraph (b) of this section, or restrict its participation in the period, if he or she determines that it is necessary to do so for the dog's health, condition, or well-being. The exemption or restriction must be recorded by the attending veterinarian. The attending veterinarian must review the grant of exemption or restriction and observe the animal at least every 30 days to determine whether it is still necessary.

§ 3.8 Feeding.

(a) Dogs and cats must be fed at least once each day, except as otherwise might be required to provide adequate veterinary care. The food must be uncontaminated, wholesome, palatable, and of sufficient quantity and nutritive value to maintain the normal condition and weight of the animal. It must be appropriate for the individual animal's age.

(b) Food receptacles must be used for dogs and cats, must be readily accessible to all dogs and cats, and must be located so as to minimize contamination by excreta and pests, and be protected from rain and snow. Feeding pans must either be made of durable material that can be easily cleaned and sanitized or be disposable. If the food receptacles are not disposable, they must be cleaned daily and must be sanitized in accordance with § 3.10(b)(3) of this subpart at least every 2 weeks, and before being used to feed a different dog or cat or social grouping of dogs or cats. If the food receptacles are disposable, they must be discarded after one use. Self-feeders may be used for the feeding of dry food. If self-feeders are used, they must be cleaned and sanitized as needed in accordance with § 3.10(b)(3) of this subpart. Measures must be taken to ensure there is no molding, deterioration, and caking of feed.

§ 3.9 Watering.

If potable water is not continually available to the dogs and cats, it must be offered to the dogs and cats at least twice daily for periods of not less than 1 hour each time, unless restricted by the attending veterinarian. Water receptacles must be kept clean and must be sanitized in accordance with § 3.10(b)(3) of this subpart at least once every 2 weeks, and before being used to water a different dog or cat or social grouping of dogs or cats.

§ 3.10 Cleaning, sanitization, housekeeping, and pest control.

(a) Cleaning of primary enclosures. Excreta and food waste must be removed from primary enclosures, and from under primary enclosures, at least daily, or more frequently if necessary to prevent an excessive accumulation of feces and food waste, to prevent soiling of the dogs or cats contained in the primary enclosures, and to reduce disease hazards, insects, pests and odors. When a primary enclosure is being cleaned by steam or by hosing or flushing with water, any dog or cat in the primary enclosure must be removed to prevent it from being involuntarily wetted or injured. All standing water must be removed from the primary enclosure and animals in other primary enclosures must be protected from being contaminated with water and other wastes during the cleaning. The pans under primary enclosures with grill-type floors and the ground areas under raised runs with wire or slatted floors must be

cleaned at least daily, and as often as necessary to prevent accumulation of feces and food waste and to reduce disease hazards, pests, insects and odors.

(b) Sanitization of primary enclosures and food and water receptacles.

(1) A used primary enclosure must be cleaned and sanitized in accordance with this section before it can be used to house another dog or cat.

(2) Primary enclosures for dogs or cats must be sanitized at least once every 2 weeks using one of the methods prescribed in paragraph (b)(3) of this section, and more often if necessary to prevent an accumulation of dirt, debris, food waste, excrete, and other disease hazards.

(3) Hard surfaces of primary enclosures and food and water receptacles must be sanitized using one of the following methods:

(i) Live steam under pressure;

(ii) Washing with hot water (at least 180 °F (82.2 °C)) and soap or detergent, as with a mechanical cage washer; or

(iii) Washing all soiled surfaces with a detergent solution so as to remove all organic material and mineral buildup, and by following the washing first with a safe and effective disinfectant rinse, then with a clean water rinse.

(4) Pen, runs and outdoor housing areas using material that cannot be sanitized using the methods provided in paragraph (b)(3) of this section, such as gravel, sand, grass, or earth, must be sanitized by removing the contaminated material as necessary to prevent odors, diseases, pests, insects, and vermin infestation.

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents and other pests and vermin. Premises must be kept free of accumulations of trash, junk, waste products, and discarded matter. Weeds, grasses, and bushes must be controlled so as to facilitate cleaning of the premises and pest control, and to protect the health and well-being of the animals.

(d) Pest control. An effective program for the control of insects, external parasites affecting dogs and cats, and birds and mammals that are pests, must be established and maintained so as to promote the health and well-being of the animals and reduce contamination by pests in animal areas.

§ 3.11 Employees.

Each person subject to the Animal Welfare regulations maintaining dogs and cats must have enough employees to carry out the level of husbandry practices and care required in this subpart. The employees who provide for husbandry and care, or handle animals, must be supervised by an animal caretaker who has the knowledge, background, and experience in proper husbandry and care of dogs and cats to supervise others. The employer must be certain that the supervisor and other employees can perform to these standards.

§ 3.12 Social grouping.

Dogs and cats housed in the same primary enclosure must be maintained in compatible groups, with the following restrictions:

(a) Females in heat (estrus) may not be housed in the same primary enclosure with males, except for breeding purposes;

(b) Any dog or cat exhibiting a vicious or overly aggressive disposition must be housed separately;

(c) Puppies or kittens 180 days of age or less may not be housed in the same primary enclosure with adult dogs or cats other than their dams, except when permanently maintained in breeding colonies;

(d) Dogs or cats may not be housed in the same primary enclosure with any other species of animals, unless they are compatible;

(e) Dogs and cats under quarantine or treatment for a communicable disease must be separated from other dogs and cats and other susceptible species of animals to minimize the risk of spread of the disease.

Transportation Standards

§ 3.13 Consignments to carriers and intermediate handlers.

(a) Carriers and intermediate handlers must not accept a dog or cat for transport in commerce more than 4 hours before the scheduled departure time of the primary conveyance on which the animal is to be transported. However, a carrier or intermediate handler may agree with anyone consigning a dog or cat to extend this time by up to 2 hours.

(b) Carriers and intermediate handlers must not accept a dog or cat for transport in commerce unless they are provided with the name, address, and phone number of the consignee.

(c) Carriers and intermediate handlers must not accept a dog or cat for transport in commerce unless written instructions concerning in-transit food and water requirements for each dog and cat in the shipment are securely attached to the outside of its primary enclosure in a manner that makes them easily noticed and read.

(d) Carriers and intermediate handlers must not accept a dog or cat for transport in commerce unless the consignor certifies in writing to the carrier or intermediate handler that the dog or cat was offered food during the 12 hours and water during the 4 hours before delivery to the carrier or intermediate handler, and specifies the date and time the dog or cat was last offered food and water. A copy of the certification must accompany the dog or cat to its destination and must include the following information for each primary enclosure:

(1) The consignor's name and address;

(2) The tag number or tattoo assigned to each dog or cat under § 2.50 of the regulations;

(3) A statement by the consignor certifying that each dog or cat contained in the primary enclosure was offered food within 12 hours and water within 4 hours before delivery to the carrier or intermediate handler, and the date and time food and water was last offered; and

(4) The consignor's signature and the date and time the certification was signed.

(e) Carriers and intermediate handlers must not accept a dog or cat for transport in commerce in a primary enclosure unless the primary enclosure meets the requirements of § 3.14 of this subpart, or the consignor certifies in writing to the carrier or intermediate handler that the primary enclosure meets the requirements of § 3.14 of this subpart. Even if the consignor provides this certification, a carrier or intermediate handler must not accept a dog or cat for transport if the primary enclosure is obviously defective or damaged and cannot reasonably be expected to safely and comfortably contain the dog or cat without causing suffering or injury. A copy of the certification must accompany the dog or cat to its destination and must include the following information for each primary enclosure:

(1) The consignor's name and address;

(2) The tag number or tattoo assigned to each dog or cat under § 2.50 of the regulations;

(3) A statement by the consignor certifying that each primary enclosure in the shipment meets the standards for primary enclosures in § 3.14 of this subpart; and

(4) The consignor's signature and the date the certification was signed.

(f) Carriers and intermediate handlers must not accept a dog or cat for transport in commerce unless their holding area and cargo facilities meet the minimum temperature requirements provided in §§ 3.18 and 3.19 of this subpart, or unless the consignor provides them with a certificate signed by a veterinarian and dated no more than 10 days before delivery of the animal to the carrier or intermediate handler for transport in commerce, certifying that the animal is acclimated to temperatures lower than those required in §§ 3.18 and 3.19 of this subpart. Even if the carrier or intermediate handler receives this certification, the temperatures the dog or cat is exposed to while in the carrier's or intermediate handler's custody must not be lower than the minimum temperature specified by the veterinarian in accordance with paragraph (f)(3) of this section. A copy of the certification must accompany the dog or cat to its destination and must include the following information:

(1) The consignor's name and address;

(2) The tag number or tattoo assigned to each dog or cat under § 2.50 of the regulations;

(3) A statement by a veterinarian, and dated no more than 10 days before delivery, that to the best of his or her knowledge, each of the dogs or cats contained in the primary enclosure is acclimated to air temperatures lower than 45 °F (7.2 °C), but now lower than a minimum temperature, specified on the certificate, that the veterinarian has determined is based on generally accepted temperature standards for the age, condition, and breed of the animals; and

(4) The signature of the veterinarian and the date the certification was signed.

(g) When a primary enclosure containing a dog or cat has arrived at the animal holding area at a terminal facility after transport, the carrier or intermediate handler must attempt to notify the consignee upon arrival and at least once in every 6-hour period thereafter. The time, date, and method of each attempted notification and the actual notification of the consignee, and the name of the person who notifies or attempts to notify the consignee must be written on the carrier's or intermediate handler's copy of the shipping document and on the copy that accompanies the primary enclosure. If the consignee cannot be notified within 24 hours after the dog or cat has arrived at the terminal facility, the carrier or intermediate handler must return the animal to the consignor or to whomever the consignor designates. If the consignee is notified of the arrival and does not accept delivery of the dog or cat within 48 hours after arrival of the dog or cat, the carrier or intermediate handler must return the animal to the consignor or to whomever the consignor designates. The carrier or intermediate handler must continue to provide proper care, feeding, and housing to the dog or cat, and maintain the dog or cat in accordance with generally accepted professional and husbandry practices until the consignee accepts delivery of the dog or cat or until it is returned to the consignor or to whomever the consignor designates. The carrier or intermediate handler must obligate the consignor to reimburse the carrier or intermediate handler for the cost of return transportation and care.

§ 3.14 Primary enclosures used to transport live dogs and cats.

Any person subject to the Animal Welfare regulations must not transport or deliver for transport in commerce a dog or cat unless the following requirements are met:

(a) *Construction of primary enclosures.* The dog or cat must be contained in a primary enclosure such as a compartment, transport cage, carton, or crate. Primary enclosures used to transport dogs and cats must be constructed so that:

(1) The primary enclosure is strong enough to contain the dogs and cats securely and comfortably and to withstand the normal rigors of transportation;

(2) The interior of the primary enclosure has no sharp points or edges and no protrusions that could injure the animal contained in it;

(3) The dog or cat is at all times securely contained within the enclosure and cannot put any part of its body outside the enclosure in a way that could result in injury to itself, to handlers, or to persons or animals nearby;

(4) The dog or cat can be easily and quickly removed from the enclosure in an emergency;

(5) Unless the enclosure is permanently affixed to the conveyance, adequate devices such as handles or handholds are provided on its exterior, and enable the enclosure to be lifted without tilting it, and ensure that anyone handling the enclosure will not come into physical contact with the animal contained inside;

(6) Unless the enclosure is permanently affixed to the conveyance, it is clearly marked on top and on one or more sides with the words "Live Animals," in letters at least 1 inch (2.5 cm.) high, and with arrows or other markings to indicate the correct upright position of the primary enclosure;

(7) Any material, treatment, paint, preservative, or other chemical used in or on the enclosure is nontoxic to the animal and not harmful to the health or well-being of the animal;

(8) Proper ventilation is provided to the animal in accordance with paragraph (c) of this section; and

(9) The primary enclosure has a solid, leak-proof bottom or a removable, leak-proof collection tray under a slatted or wire mesh floor that prevents seepage of waste products, such as excreta and body fluids, outside of the enclosure. If a slatted or wire mesh floor is used in the enclosure, it must be designed and constructed so that the animal cannot put any part of its body between the slats or through the holes in the mesh. Unless the dogs or cats are on raised slatted floors or raised floors made of wire mesh, the primary enclosure must contain enough previously unused litter to absorb and cover excreta. The litter must be of a suitably absorbent material that is safe and nontoxic to the dogs and cats.

(b) *Cleaning of primary enclosures.* A primary enclosure used to hold or transport dogs or cats in commerce must be cleaned and sanitized before each use in accordance with the methods provided in § 3.10(b)(3) of this subpart. If the dogs or cats are in transit for more than 24 hours, the enclosures must be cleaned and any litter replaced, or other methods, such as moving the animals to another enclosure, must be utilized to prevent the soiling of the dogs or cats by body wastes.

(c) *Ventilation.* (1) Unless the primary enclosure is permanently affixed to the conveyance, there must be ventilation openings on all four walls of the primary enclosure. The ventilation openings must total at least 8 percent of the surface area of each wall, and the total surface area of all the ventilation openings must be at least 14 percent of the total surface area of all four walls of the primary enclosure. Additionally, at least one-third of the total minimum area required for ventilation must be located on the upper one-half of the primary enclosure;

(2) Unless the primary enclosure is permanently affixed to the conveyance, projecting rims or similar devices must be located on the exterior of each enclosure wall having a ventilation opening, in order to prevent obstruction of the openings. The projecting rims or similar devices must be large enough to provide a minimum air circulation space of 0.75 in. (1.9 cm) between the primary

enclosure and anything the enclosure is placed against.

(3) If a primary enclosure is permanently affixed to the primary conveyance so that there is only a front ventilation opening for the enclosure, the primary enclosure must be affixed to the primary conveyance in such a way that the front ventilation opening cannot be blocked, and the front ventilation opening must open directly to an unobstructed aisle or passageway inside the conveyance. The ventilation opening must be at least 90 percent of the total area of the front wall of the enclosure, and must be covered with bars, wire mesh, or smooth expanded metal having air spaces.

(d) *Compatibility.* (1) Live dogs or cats transported in the same primary enclosure must be of the same species and be maintained in compatible groups, except that dogs and cats that are private pets, are of comparable size, and are compatible, may be transported in the same primary enclosure.

(2) Puppies or kittens 180 days of age or less may not be transported in the same primary enclosure with adult dogs or acts other than their dams.

(3) Dogs or cats that are overly aggressive or exhibit a vicious disposition must be transported individually in a primary enclosure.

(4) Any female dog or cat in heat (estrus) may not be transported in the same primary enclosure with any male dog or cat.

(e) *Space and placement.* (1) Primary enclosures used to transport live dogs and cats must be large enough to ensure that each animal contained in the primary enclosure has enough space to turn about normally while standing, to stand and sit erect, and to lie in a natural position.

(2) Primary enclosures used to transport dogs and cats must be positioned in the primary conveyance so as to provide protection from the elements.

(f) *Transportation by air.* (1) No more than two live dogs or cats, 6 months of age or older, that are of comparable size, may be transported in the same primary enclosure when shipped via air carrier, and only if all other requirements in this section are met.

(2) No more than two live puppies, 8 weeks to 6 months of age, that are of comparable size, and weighing over 20 lb (9 kg) each, may be transported in the same primary enclosure when shipped via air carrier, and only if all other requirements in this section are met.

(3) No more than three live puppies or kittens, 8 weeks to 6 months of age, that are of comparable size, and weighing 20 lb (9 kg) or less each, may be transported in the same primary enclosure when shipped via air carrier, and only if all other requirements in this section are met.

(4) Weaned live puppies or kittens less than 8 weeks of age and of comparable size, or puppies or kittens that are less than 8 weeks of age that are littermates and are accompanied by their dam, may be transported in the same primary enclosure when shipped to research facilities, including federal research facilities.

(g) *Transportation by surface vehicle.* (1) No more than four live dogs or cats, 8 weeks of age or older, that are of comparable size, may be transported in the same primary enclosure when shipped by surface vehicle (including ground and water transportation) and only if all other requirements of this section are met.

(2) Weaned live puppies or kittens less than 8 weeks of age and of comparable size, or puppies or kittens that are less than 8 weeks of age that are littermates and are accompanied by their dam, may be transported in the same primary enclosure when shipped to research facilities, including federal research facilities.

(h) *Accompanying documents and records.* Shipping documents that must accompany shipments of dogs and cats may be held by the operator of the primary conveyance, for surface transportation only, or must be securely attached in a readily accessible manner to the outside of any primary enclosure that is part of the shipment, in a manner that allows them to be detached for examination and securely reattached, such as in a pocket or sleeve. Instructions for food and water and for administration of drugs, medication, and other special care must be attached to each primary enclosure in a manner that makes them easy to notice, to detach for examination, and to reattach securely.

§ 3.15 Primary conveyances (motor vehicle, rail, air, and marine).

(a) The animal cargo space of primary conveyances used to transport dogs and cats must be designed, constructed, and maintained in a manner that at all times protects the health and well-being of the animals transported in them, ensures their safety and comfort, and prevents the entry of engine exhaust from the primary conveyance during transportation.

(b) The animal cargo space must have a supply of air that is sufficient for the normal breathing of all the animals being transported in it.

(c) Each primary enclosure containing dogs or cats must be positioned in the animal cargo space in a manner that provides protection from the elements and that allows each dog or cat enough air for normal breathing.

(d) During air transportation, including time spent on the ground, dogs and cats must be held or transported in cargo areas that are heated or cooled as necessary to maintain anambient temperature that ensures the health and comfort of the dogs or cats. The cargo areas must be pressurized when the primary conveyance used for air transportation is not on the ground.

(e) During surface transportation, auxiliary ventilation, such as fans, blowers or air conditioning, must be used in any animal cargo space containing live dogs and cats when the ambient temperature within the animal cargo space reaches 85 °F (29.5 °C). Moreover, the ambient temperature may not exceed 95 °F (35 °C) at any time; nor exceed 85 °F (29.5 °C) for a period of more than 4 hours; nor fall below 45 °F (7.2 °C) for a period of more than 4 hours; nor fall below 35 °F (1.7 °F) at any time.

(f) Primary enclosures must be positioned in the primary conveyance in a manner that allows the dogs and cats to be quickly and easily removed from the primary conveyance in an emergency.

(g) The interior of the animal cargo space must be kept clean.

(h) Live dogs and cats may not be transported with any material, substance (e.g., dry ice) or device in a manner that may reasonably be expected to harm the dogs and cats or cause inhumane conditions, unless proper precaution is taken to prevent the injury or inhumane conditions.

§ 3.16 Food and water requirements.

(a) Each dog and cat that is 16 weeks of age or more must be offered food at least once every 24 hours. Puppies and kittens less than 16 weeks of age must be offered food at least once every 12 hours. These time periods apply to dealers, exhibitors, research facilities, including federal research facilities, who transport dogs and cats in their own primary conveyance, starting from the time the dog or cat was last offered food before transportation was begun. These time periods apply to carriers and intermediate handlers starting from the date and time stated on the certificate provided under § 3.13(d). Each dog or cat must be offered food within 12 hours before being transported in commerce. Consignors who are subject to the Animal Welfare regulations must certify that each dog and cat was offered food within the 12 hours preceding delivery of the dog or cat to a carrier or

intermediate handler for transportation in commerce, and must certify the date and time of the feeding, in accordance with § 3.13(d).

(b) Each dog and cat must be offered potable water during the 4 hours immediately preceding the beginning of its transportation in commerce and at least once every 12 hours thereafter. This time period applies to dealers, exhibitors, and research facilities, including federal research facilities, who transport dogs and cats in their own primary conveyance, starting from the time the dog or cat was last offered potable water before being transported in commerce. This time period applies to carriers and intermediate handlers starting from the date and time stated on the certificate provided under § 3.13(d). Consignors who are subject to the Animal Welfare regulations must certify that each dog and cat was offered potable water within 4 hours before being transported in commerce, and must certify the date and time the water was offered, in accordance with § 3.13(d).

(c) Any dealer, research facility, including a federal research facility, or exhibitor offering any dog or cat to a carrier or intermediate handler for transportation in commerce must securely attach to the outside of the primary enclosure used for transporting the dog or cat, written instructions for the in-transit food and water requirements for the dogs and cats contained in the enclosure. The instructions must be attached in a manner that makes them easily noticed, detached and returned to the enclosure.

(d) Food and water receptacles must be securely attached inside the primary enclosure and placed so that the receptacles can be filled from outside the enclosure without opening the door. Food and water containers must be designed, constructed, and installed so that a dog or cat cannot leave the primary enclosure through the food or water opening.

§ 3.17 Care in transit.

(a) Surface transportation (ground and water). Any person subject to the Animal Welfare regulations transporting dogs or cats in commerce must ensure that the operator of the conveyance, or a person accompanying the operator, observes the dogs or cats as often as circumstance allow, but not less than once every 4 hours, to make sure they have sufficient air for normal breathing, that the ambient temperature is within the limits provided in § 3.15(e), and that all applicable standards of this subpart are being complied with. The regulated person must ensure that the operator or person accompanying the operator determines whether any of the dogs or cats are in obvious physical distress and obtains any veterinary care needed for the dogs or cats at the closest available veterinary facility.

(b) Air transportation. During air transportation of dogs or cats, it is the responsibility of the carrier to observe the dogs or cats as frequently as circumstance allow, but not less than once every 4 hours if the animal cargo area is accessible during flight. If the animal cargo area is not accessible during flight, the carrier must observe the dogs or cats whenever they are loaded and unloaded and whenever the animal cargo space is otherwise accessible to make sure they have sufficient air for normal breathing, that the animal cargo area meets the heating and cooling requirements of § 3.15(d), and that all other applicable standards of this subpart are being complied with. The carrier must determine whether any of the dogs or cats are in obvious physical distress, and arrange for any needed veterinary care as soon as possible.

(c) If a dog or cat is obviously ill, injured, or in physical distress, it must not be transported in commerce, except to receive veterinary care for the condition.

(d) During transportation in commerce, a dog or cat must not be removed from its primary enclosure unless it is placed in another primary enclosure or facility that meets the requirements of § 3.6 or § 3.14 of this subpart.

(e) The transportation regulations contained in this subpart must be complied with until the dog or cat reaches its final destination, or until the consignee takes physical delivery of the animal if the animal is consigned for transportation.

§ 3.18 Terminal facilities.

(a) *Placement.* Any person subject to the Animal Welfare regulations must not commingle shipments of dogs or cats with inanimate cargo in animal holding areas of terminal facilities.

(b) *Cleaning, sanitization, and pest control.* All animal holding areas of terminal facilities must be cleaned and sanitized in a manner prescribed in § 3.10(b)(3) of this subpart, as often as necessary to prevent an accumulation of debris or excreta and to minimize vermin infestation and disease hazards. Terminal facilities must follow an effective program in all animal holding areas for the control of insects, ectoparasites, and birds and mammals that are pests to dogs and cats.

(c) *Ventilation.* Air, preferably fresh air, must be provided in any animal holding area in a terminal facility containing dogs or cats, by means of windows, doors, vents, or air conditioning. The air must be circulated by fans, blowers, or air conditioning so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans, vents, fans, blowers, or air conditioning must be used in any animal holding area containing dogs and cats, when the ambient temperature is 75° F (23.9° C) or higher.

(d) *Temperature.* The ambient temperature in an animal holding area containing dogs or cats must not fall below 45° F (7.2° C) or rise above 75° F (23.9° C) for more than four consecutive hours at any time dogs or cats are present. The ambient temperature must not fall below 35° F (1.7° C) or rise above 85° F (29.5° C) at any time dogs or cats are present. The ambient temperature must be measured in the animal holding area by the carrier, intermediate handler, or a person transporting dogs or cats who is subject to the Animal Welfare regulations, outside any primary enclosure containing a dog or cat at a point not more than 3 feet (0.91 m) away from an outside wall of the primary enclosure, and approximately midway up the side of the enclosure.

(e) *Shelter.* Any person subject to the Animal Welfare regulations holding a live dog or cat in an animal holding area of a terminal facility must provide the following:

(1) Shelter from sunlight and extreme heat. Shade must be provided that is sufficient to protect the dog or cat from the direct rays of the sun.

(2) Shelter from rain or snow. Sufficient protection must be provided to allow the dogs and cats to remain dry during rain, snow, and other precipitation.

(f) *Duration.* The length of time any person subject to the Animal Welfare regulations can hold dogs and cats in animal holding areas of terminal facilities upon arrival is the same as that provided in § 3.13(g).

§ 3.19 Handling

(a) Any person subject to the Animal Welfare regulations who moves (including loading and unloading) dogs or cats within, to, or from the animal holding area of a terminal facility or a primary conveyance must do so as quickly and efficiently as possible and

must provide the following during movement of the dog or cat:

(1) *Shelter from sunlight and extreme heat.* Sufficient shade must be provided to protect the dog or cat from the direct rays of the sun. The dog or cat must not be exposed to an ambient air temperature above 85° F (29.5° C) for a period of more than 45 minutes while being moved to or from a primary conveyance or a terminal facility. The temperature must be measured in the manner provided in § 3.18(d) of this subpart.

(2) *Shelter from rain and snow.* Sufficient protection must be provided to allow the dog and cat to remain dry during rain, snow, and other precipitation.

(3) *Shelter from cold temperatures.* Transporting devices on which live dogs or cats are placed to move them must be covered to protect the animals when the outdoor temperature falls below 50° F (10° C). The dogs or cats must not be exposed to an ambient temperature below 45° F (7.2° C) for a period of more than 45 minutes, unless they are accompanied by a certificate of acclimation to lower temperatures as provided in § 3.13(f). The temperature must be measured in the manner provided in § 3.18(d) of this subpart.

(b) Any person handling a primary enclosure containing a dog or cat must use care and must avoid causing physical or emotional distress to the dog or cat.

(1) A primary enclosure containing a live dog or cat must not be placed on unattended conveyor belts, or on elevated conveyor belts, such as baggage claim conveyor belts and inclined conveyor ramps that lead to baggage claim areas, at any time; except that a primary enclosure may be placed on inclined conveyor ramps used to load and unload aircraft if an attendant is present at each end of the conveyor belt.

(2) A primary enclosure containing a dog or cat must not be tossed, dropped, or needlessly tilted, and must not be stacked in a manner that may reasonably be expected to result in its falling. They must be handled and positioned in the manner that written instructions and arrows on the outside of the primary enclosure indicate.

(c) The regulations in this section apply to movement of a dog or cat from primary conveyance to primary conveyance, within a primary conveyance or terminal facility, and to or from a terminal facility or a primary conveyance.

3. In § 3.28, paragraph (b)(2) (i) and (ii) and (b)(3) (i) and (iii) would be revised to read as follows:

§ 3.28 Primary enclosures.

* * * * *

(b) * * *

(2) * * *

(i) The interior height of any primary enclosure used to confine guinea pigs must be at least 7 inches (17.78 cm).

(ii) Each guinea pig must be provided a minimum amount of floor space in any primary enclosure as follows:

Weight or stage of maturity	Minimum floor space per hamster	
	in²	cm²
Weaning to 350 grams	60	387.12
>350 grams or nursing females with their litters	101	651.65

(3) * * *

(i) The interior height of any primary enclosure used to confine hamsters must be at least 6 inches (15.24 cm).

* * * * *

(iii) Except as provided in paragraph (b)(3)(ii) of this section, each hamster must be provided a minimum amount of floor space in any primary enclosure as follows:

Weight		Minimum floor space per hamster	
g	ozs	in²	cm²
60	2.1	10	64.52
60 to 80	2.1–2.8	13	83.88
80 to 100	2.8–3.5	16	103.23
>100	> 3.5	19	122.59

4. In § 3.36, the introductory text would be revised to read as follows:

§ 3.36 Primary enclosures used to transport live guinea pigs and hamsters.

No person subject to the Animal Welfare regulations is allowed to offer for transportation, or transport, in commerce any live guinea pig or hamster in a primary enclosure that does not conform to the following requirements.

* * * * *

5. In § 3.37, a new paragraph (g) would be added to read as follows:

§ 3.37 Primary conveyances (motor vehicle, rail, air, and marine).

* * * * *

(g) The animal cargo space of primary conveyances used to transport guinea pigs or hamsters must be mechanically sound and provide fresh air by means of windows, doors, vents, or air conditioning so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as fans, blowers, or air conditioners, must be used in any cargo space containing live guinea pigs or hamsters when the ambient temperature in the animal cargo space is 75° F (23.9° C) or higher. The ambient temperature within the animal cargo space must not be allowed to exceedd 85° F (29.5° C) or to fall below 45° F (7.2° C), except that the ambient temperature in the cargo space may be below 45° F (7.2° C) for hamsters if the hamsters are accompanied by a certificate of acclimation to lower temperatures, as provided in § 3.35(c) of this part.

6. In § 3.40, the first two sentences would be revised to read as follows:

§ 3.40 Terminal facilities.

No person subject to the Animal Welfare regulations is allowed to commingle shipments of live guinea pigs or hamsters with inanimate cargo. All animal holding areas of a terminal facility where shipments of live guinea pigs or hamsters are maintained must be cleaned and sanitized as prescribed in § 3.31 of the standards often enough to prevent an accumulation of debris or excreta, to minimize vermin infestation, and to prevent a disease hazard. * * *

7. In § 3.41 paragraph (a) introductory text would be revised to read as follows:

§ 3.41 Handling.

(a) Any person who is subject to the Animal Welfare Regulations and who moves live guinea pigs or hamsters from an animal holding area of a terminal facility to a primary conveyance and vice versa must do so as quickly and efficiently as possible. Any person subject to the Animal Welfare Act and holding any live guinea pig or hamster in an animal holding area of a terminal facility or transporting any live guinea pig or hamster to or from a terminal facility must provide the following:

* * * * *

8. In § 3.53, the table in paragraph (b) would be revised to read as follows:

§ 3.53 Primary enclosures.

* * * * *

(b) * * *

	Individual weights		Minimum floor space		Minimum interior height	
	kg	lbs	m^2	ft^2	cm	in
Individual rabbits (weaned)	2	4.4	0.14	1.5	35.56	14
	2–4	4.4–8.8	0.28	3.0	35.56	14
	4–5.4	8.8–11.9	0.37	4.0	35.56	14
	>5.4	>11.9	0.46	5.0	35.56	14

	Weight of nursing female		Minimum floor space/ female & litter		Minimum interior height	
	kg	lbs	m^2	ft^2	cm	in
Females with litters	2	4.4	0.37	4.0	35.56	14
	2–4	4.4–8.8	0.46	5.0	35.56	14
	4–5.4	8.8–11.9	0.56	6.0	35.56	14
	>5.4	>11.9	0.70	7.0	35.56	14

9. In § 3.61, the introductory paragraph would be revised to read as follows:

§ 3.61 Primary enclosures used to transport live rabbits.

No person subject to the Animal Welfare regulations is allowed to offer for transportation or to transport in commerce any live rabbit in a primary enclosure that does not conform to the following requirements.

* * * * *

10. In § 3.62, a new paragraph (g) would be added to read as follows:

§ 3.62 Primary conveyances (motor vehicle, rail, air, and marine).

* * * * *

(g) The animal cargo space of primary conveyances used to transport rabbits must be mechanically sound and provide fresh air by means of windows, doors, vents, or air conditioning so as to mimimize drafts, odors, and mositure condensation. Auxiliary ventilation, such as fans, blowers, or air conditioners, must be used in any cargo space containing live rabbits when the ambient temperature in the animal cargo space is 75 °F (23.9 °C) or higher. The ambient temperature within the animal cargo space must not be allowed to exceed 85 °F (29.5 °C) or to fall below 45° (7.2 °C), except that the ambient temperature in the cargo space may be below 45°F (7.2 °C) if the rabbits are accompanied by a certificate of acclimation to lower temperatures, as described in § 3.60(c) of this part.

11. In § 3.65 the first two sentences would be revised to read as follows:

§ 3.65 Terminal facilities.

No person subject to the Animal Welfare regulations may commingle shipments of live rabbits with inanimate cargo. All animal holding areas of a terminal facility where shipments of rabbits are maintained must be cleaned and sanitized as prescribed in § 3.56 of the standards often enough to prevent an accumulation of debris or excreta, to minimize vermin infestation, and to prevent a disease hazard. * * *

12. In § 3.66, paragraph (a) would be revised to read as follows:

§ 3.66 Handling.

(a) Any person who is subject to the Animal Welfare regulations and who moves live rabbits from an animal holding area of a terminal facility to a primary conveyance and vice versa must do so as quickly and efficiently as possible. Any person subject to the Animal Welfare regulations and holding any live rabbit in an animal holding area of a terminal facility or transporting any live rabbit to or from a terminal facility must provide the following:

* * * * *

13. Subpart D, consisting of §§ 3.75 through 3.93, would be revised to read as follows:

Subpart D—Specifications for the Humane Handling, Care, Treatment, and Transportation of Nonhuman Primates

Facilities and Operating Standards

Sec.

3.75 Housing facilities, general.
3.76 Indoor housing facilities.
3.77 Sheltered housing facilities.
3.78 Outdoor housing facilities.
3.79 Mobile or traveling housing facilities.
3.80 Primary enclosure.
3.81 Additional requirements for research facilities.

Animal Health and Husbandry Standards

3.82 Feeding.
3.83 Watering.
3.84 Cleaning, sanitization, housekeeping, and pest control.
3.85 Employees.
3.86 Social grouping and separation.

Sec.

Transportation Standards

3.87 Consignments to carriers and intermediate handlers.
3.88 Primary enclosures used to transport nonhuman primates.
3.89 Primary conveyances (motor vehicle, rail, air, and marine).
3.90 Food and water requirements.
3.91 Care in transit.
3.92 Terminal facilities.
3.93 Handling.

Subpart D—Specifications for the Humane Handling, Care, Treatment, and Transportation of Nonhuman Primates.[1]

Facilities and Operating Standards

§ 3.75 Housing facilities, general.

(a) *Structure; construction.* Housing facilities for nonhuman primates must be designed and constructed so that they are structurally sound for the species of nonhuman primates housed in them. They must be kept in good repair, and they must protect the animals from injury, contain the animals securely, and

[1] Nonhuman primates include a great diversity of forms, ranging from the marmoset weighing only a few ounces, to the adult gorilla weighing hundreds of pounds, and including more than 240 species. They come from Asia, Africa, and Central and South America, and they live in different habitats in nature. Some have been transported to the United States from the natural habitats and some have been raised in captivity in the United States. Their nutritional and activity requirements differ, as do their social and environmental requirements. As a result, the conditions appropriate for one species do not necessarily apply to another. Accordingly, these minimum specifications must be applied in accordance with the customary and generally accepted professional and husbandry practices considered appropriate for each species, and necessary to promote their psychological well-being.

These minimum standards apply only to live nonhuman primates, unless stated otherwise.

restrict other animals and unauthorized humans from entering.

(b) *Condition and site.* Housing facilities and areas used for storing animal food or bedding must be free of any accumulation of trash, waste material, junk, weeds, and other discarded materials. Animal areas inside of housing facilities must be kept neat and free of clutter, including equipment, furniture, or stored material, but may contain materials actually used and necessary for cleaning the area, such as brooms, mops, mop buckets, trash containers, and fixtures necessary for proper husbandry practices, such as tables, cabinets, and sinks. Housing facilities other than those maintained by research facilities and federal research facilities must be physically separated from any other businesses. If a housing facility is located on the same premises as any other businesses, it must be physically separated from the other businesses so that unauthorized humans, and animals the size of dogs, skunks, and raccoons, are prevented from entering it.

(c) *Surfaces.*—(1) *General requirements.* The surfaces of housing facilities—including perches, shelves, swings, boxes, houses, dens, and other furniture-type fixtures or objects within the facility—must be constructed in a manner and made of materials that allow them to be readily cleaned and sanitized, or removed or replaced when worn or soiled. Furniture-type fixtures or objects must be sturdily constructed and must be strong enough to provide for the safe activity and welfare of nonhuman primates. Outdoor floors may be made of dirt, sand, gravel, grass, or other similar material that can be readily cleaned, or can be removed or replaced whenever cleaning does not eliminate odors, diseases, pests, insects, or vermin. Any surfaces that come in contact with nonhuman primates must:

(i) Be free of rust that prevents the required cleaning and sanitization, or that affects the structural strength of the surface; and

(ii) Be free of jagged edges or sharp points that might injure the animals.

(2) Maintenance and replacement of surfaces. All surfaces must be maintained on a regular basis. Surfaces of housing facilities—including houses, dens, and other furniture-type fixtures and objects within the facility—that cannot be readily cleaned and sanitized, must be replaced when worn or soiled.

(3) *Cleaning.* Hard surfaces with which nonhuman primates come in contact must be cleaned daily and sanitized at least once every two weeks and as often as necessary to prevent any accumulation of excreta or disease hazards, unless the species housed in the facility engage in scent marking. If the species scent mark, the surfaces must be sanitized at regular intervals determined in accordance with generally accepted professional and husbandry practices and they must be spot cleaned daily. Floors made of dirt, sand, gravel, grass, or other similar material, and planted enclosures must be raked and spot-cleaned daily. Contaminated material must be removed or replaced whenever raking and spot cleaning does not eliminate odors, diseases, insects, pests, or vermin infestation. All other surfaces of housing facilities must be cleaned daily and sanitized when necessary to satisfy generally accepted husbandry standards and practices. Sanitization may be done by any of the methods provided in § 3.84(b)(3) for primary enclosures.

(d) *Water and electric power.* The housing facility must have reliable electric power adequate for heating, cooling, ventilation, and lighting, and for carrying out other husbandry requirements in accordance with the regulations in this subpart. The housing facility must provide mechanically pressurized running potable water for the nonhuman primates' drinking needs. It must be adequate for cleaning and for carrying out other husbandry requirements.

(e) *Storage.* Supplies of food and bedding must be stored in leakproof containers that protect the supplies from spoilage, contamination, and vermin infestation. The supplies must be stored off the floor and away from the walls, to allow cleaning underneath and around the supplies. Perishable food must be refrigerated, and all food must be stored in a manner that prevents contamination and deterioration of its nutritive value. Only the food and bedding currently being used may be kept in animal areas, and when not in actual use, open food and bedding supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination. Substances that are toxic to a nonhuman primate must not be stored in animal areas, or in food storage or preparation areas.

(f) *Drainage and waste disposal.* Housing facility operators must provide daily (or more often as necessary) removal and disposal of animal and food wastes, bedding, dead animals, debris, garbage, water, and any other fluids and wastes. Housing facilities must be equipped with disposal facilities and drainage systems that are constructed and operated so that animal wastes and water are rapidly eliminated and the animals stay dry. Disposal and drainage systems must minimize vermin and pest infestation, insects, odors, and disease hazards. All drains must be properly constructed, installed, and maintained. If closed drainage systems are used, they must be equipped with traps and prevent the backflow of gases and the backup of sewage onto the floor. If the facility uses sump ponds, settlement ponds, or other similar systems for drainage and animal waste disposal, the system must be located for enough away from the animal area of the housing facility to prevent odors, diseases, insects, pests, and vermin infestation. If drip or constant flow watering devices are used to provide water to the animals, excess water must be rapidly drained out of the animal areas by gutters or pipes so that the animals stay dry. Puddles of water in animal areas must be promptly mopped up or drained so that the animals stay dry. Trash containers in housing facilities and in food storage and food preparation areas must be leakproof and must have tightly fitted lids on them at all times. Dead animals, animal parts, and animal waste must not be kept in food storage or food preparation areas, food freezers, food refrigerators, and animal areas.

(g) *Washrooms and sinks.* Washing facilities, such as washrooms, basins, sinks, or showers must be provided for animal caretakers and must be readily accessible

§ 3.78 Indoor housing facilities.

(a) *Heating, cooling, and temperate.* Indoor housing facilities must be sufficiently heated and cooled when necessary to protect nonhuman primates from cold and hot temperatures and to provide for their health, comfort and well-being. The ambient temperature in the facility must not fall below 50 °F (10 °C) and must not rise above 85 °F (29.5 °C) when nonhuman primates are present. Within this range, the ambient temperature must be maintained at a level that ensures the health and well-being of the species housed, in accordance with generally accepted professional and husbandry practices.

(b) *Ventilation.* Indoor housing facilities must be sufficiently ventilated at all times when nonhuman primates are present to provide for their health, comfort, and well-being and to minimize odors, drafts, ammonia levels, and moisture condensation. Air, preferably fresh air, must be provided by windows, doors, vents, fans, or air conditioning. The relative humidity must be maintained between 30 percent and 70 percent. Within this range, the relative humidity maintained must be at a level that ensures the health and well-being of

the species housed, in accordance with generally accepted professional and husbandry practices.

(c) *Lighting.* Indoor housing facilities must be lighted well enough to permit routine inspection and cleaning of the facility, and observation of the nonhuman primates. A regular daily lighting cycle of at least 8 consecutive hours of light and at least 8 consecutive hours of darkness must be provided, by either natural or artificial light. If only artificial light, such as fluorescent light, is provided, it must provide full-spectrum illumination. Primary enclosures must be placed in the housing facility so as to protect the nonhuman primates from excessive light.

§ 3.77 Sheltered housing facilities.

(a) *Heating, cooling, and temperature.* The sheltered part of sheltered housing facilities must be sufficiently heated and cooled when necessary to protect the nonhuman primates from cold and hot temperatures and to provide for their health, comfort and well-being. The ambient temperature in the sheltered part of the facility must not fall below 50 °F (10 °C) and must not rise above 85 °F (29.5 °C). Within this range, the ambient temperature must be maintained at a level that ensures the health and well-being of the species housed, in accordance with generally accepted professional and husbandry practices.

(b) *Ventilation.* The sheltered part of sheltered animal facilities must be sufficiently ventilated at all times to provide for the health, comfort, and well-being of nonhuman primates and to minimize odors, drafts, ammonia levels, and moisture condensation. Air, preferably fresh air, must be provided by windows, doors, vents, fans, or air conditioning. The relative humidity maintained in the sheltered part of the facility must be between 30 percent and 70 percent. Within this range, the relative humidity maintained must be at a level that ensures the health and well-being of the species housed, in accordance with generally accepted professional and husbandry practices.

(c) *Lighting.* The sheltered part of sheltered housing facilities must be lighted well enough to permit routine inspection and cleaning of the facility, and observation of the nonhuman primates. A regular daily lighting cycle of at least 8 consecutive hours of light and at least 8 consecutive hours of darkness must be provided, by either natural or artificial light. If only artificial light, such as fluorescent light, is provided, it must provide full-spectrum illumination. Primary enclosures must be placed in the housing facility so as to protect the nonhuman primates from excessive light.

(d) *Shelter from the elements.* Sheltered housing facilities for nonhuman primates must provide adequate shelter from the elements at all times. It must provide protection from the sun, rain, snow, wind, and cold, and from any weather conditions that may occur.

(e) *Capacity; multiple shelters.* Both the sheltered part of sheltered housing facilities and any other necessary shelter from the elements must be sufficiently large to provide protection comfortably to all the nonhuman primates housed in the facility at the same time. If aggressive or dominant animals are housed in the facility with other animals there must be multiple shelters.

(f) *Perimeter fence.* The outdoor area of a sheltered housing facility must be enclosed by a fence that is at least 6 feet high. The fence must be constructed so that it protects nonhuman primates by preventing unauthorized humans, and animals the size of dogs, skunks, and raccoons, from going through it or under it and having contact with the nonhuman primates. It must be at least 3 feet from the outside wall or fence of the primary enclosure. A perimeter fence is not required if:

(1) the outside walls of the primary enclosure are made of a sturdy, durable material such as concrete, wood, plastic, metal, or glass, and are high enough and constructed in a manner that prevents contact with or entry by humans and animals that are outside the sheltered housing facility; or

(2) the housing facility is surrounded by a natural barrier that restricts the nonhuman primates to the housing facility and protects them from contact with unauthorized humans and animals that are outside the sheltered housing facility, and the Administrator gives written permission.

(g) *Public barriers.* Fixed public exhibits housing nonhuman primates, such as zoos, must have a barrier between the primary enclosure and the public at any time the public is present that prevents physical contact between the public and the nonhuman primates. Nonhuman primates used in trained animal acts or in uncaged public exhibits must be under the direct control and supervision of an experienced handler or trainer at all times when the public is present. Trained nonhuman primates may be permitted physical contact with the public, as allowed under § 2.131, but only if they are under the direct control and supervision of an experienced handler or trainer at all times during the contact.

§ 3.78 Outdoor housing facilities

(a) *Acclimation.* Only nonhuman primates that are acclimated to the prevailing temperature and humidity at the outdoor housing facility during the time of year they are at the facility, and that can tolerate the range of temperatures and climatic conditions known to occur at the facility at that time of year without stress or discomfort, may be kept in outdoor facilities.

(b) *Shelter from the elements.* Outdoor housing facilities for nonhuman primates must provide adequate shelter from the elements at all times. It must provide protection from the sun, rain, snow, wind, and cold, and from any weather conditions that may occur. The shelter must provide heat to the primates to prevent the ambient temperature from falling below 50 °F (10 °C).

(c) *Capacity; multiple shelters.* The shelter must be sufficiently large to comfortably provide protection for all the nonhuman primates housed in the facility at the same time. If aggressive or dominant animals are housed in the facility with other animals there must be multiple shelters.

(d) *Perimeter fence.* An outdoor housing facility must be enclosed by a fence that is at least 6 feet high. The fence must be constructed so that it protects nonhuman primates by preventing unauthorized humans, and animals the size of dogs, skunks, and raccons, from going through it or under it and having contact with the nonhuman primates. It must be at least 3 feet from the outside wall or fence of the primary enclosure. A perimeter fence is not required if:

(1) the outside walls of the primary enclosure are made of a sturdy, durable material such as concrete, wood, plastic, metal, or glass, and are high enough and constructed in a manner that prevents contact with or entry by humans and animals that are outside the housing facility; or

(2) the housing facility is surrounded by a natural barrier that restricts the nonhuman primates to the housing facility and protects them from contact with unauthorized humans and animals that are outside the housing facility, and the Administrator gives written permission.

(e) *Public barriers.* Fixed public exhibits housing nonhuman primates, such as zoos, must have a barrier between the primary enclosure and the public at any time the public is present, in order to prevent physical contact between the public and the nonhuman primates. Nonhuman primates used in

trained animal acts or in uncaged public exhibits must be under the direct control and supervision of an experienced handler or trainer at all times when the public is present. Trained nonhuman primates may be allowed physical contact with the public, but only if they are under the direct control and supervision of an experienced handler or trainer at all times during the contact.

§ 3.79 Mobile or traveling housing facilities.

(a) *Heating, cooling, and temperature.* Mobile or traveling housing facilities must be sufficiently heated and cooled when necessary to protect nonhuman primates from cold and hot temperatures and to provide for their health, comfort and well-being. The ambient temperature in the traveling housing facility must not fall below 50 °F (10 °C) and must not rise above 95 °F (35 °C) when nonhuman primates are present. Within this range, the ambient temperature must be maintained at a level that ensures the health and well-being of the species housed, in accordance with generally accepted professional and husbandry practices. Auxiliary ventilation, such as fans, blowers, or air conditioning, must be provided when the ambient temperature in the traveling housing facility is 85 °F (29.5 °C) or higher.

(b) *Ventilation.* Traveling housing facilities must be sufficiently ventilated at all times when nonhuman primates are present to provide for the health, comfort, and well-being of nonhuman primates and to minimize odors, drafts, ammonia levels, moisture condensation, and exhaust fumes. Air, preferably fresh air, must be provided by means of windows, doors, vents, fans, or air conditioning. The relative humidity must be maintained at a level that ensures the health and well-being of the species housed, in accordance with generally accepted professional and husbandry practices.

(c) *Lighting.* Mobile or traveling housing facilities must be lighted well enough to permit routine inspection and cleaning of the facility, and observation of the nonhuman primates. A regular daily lighting cycle of at least 8 consecutive hours of light and at least 8 consecutive hours of darkness must be provided, by either natural or artificial light. If only artificial light, such as fluorescent light, is provided, it must provide full-spectrum illumination. Primary enclosures must be placed in the housing facility so as to protect the nonhuman primates from excessive light.

(d) *Public barriers.* There must be a barrier between a mobile or traveling housing facility and the public at any time the public is present, in order to prevent physical contact between the nonhuman primates and the public. Nonhuman primates used in traveling exhibits, trained animal acts, or in uncaged public exhibits must be under the direct control and supervision of an experienced handler or trainer at all times when the public is present. Trained nonhuman primates may be allowed physical contact with the public, but only if they are under the direct control and supervision of an experienced handler or trainer at all times during the contact.

§ 3.80 Primary enclosures.

Primary enclosures for nonhuman primates must meet the following minimum requirements:

(a) *General requirements.* (1) Primary enclosures must be designed and constructed of suitable materials so that they are structurally sound for the species of nonhuman primates contained in them. They must be kept in good repair.

(2) Primary enclosures must be constructed and maintained so that they—

(i) Have no sharp points or edges that could injure the nonhuman primates;

(ii) Protect the nonhuman primates from injury;

(iii) Contain the nonhuman primates securely and prevent accidental opening of the enclosure, including opening by the animal, and unauthorized release of the nonhuman primates;

(iv) Keep predators and unauthorized individuals from entering the enclosure or having physical contact with the nonhuman primates;

(v) Enable the nonhuman primates to remain dry and clean;

(vi) Provide shelter and protection from extreme temperatures and weather conditions that may be uncomfortable or hazardous to the species of nonhuman primate contained;

(vii) Provide sufficient shade to shelter all the nonhuman primates housed in the primary enclosure at one time;

(viii) Provide the nonhuman primates with easy and convenient access to clean food and water;

(ix) Enable all surfaces in contact with nonhuman primates to be readily cleaned and sanitized in accordance with § 3.84(b)(3), or replaced when worn or soiled;

(x) Have floors that are constructed in a manner that protects the nonhuman primates from injuring themselves or from having their appendages caught; and

(xi) Provide sufficient space for the nonhuman primates to make normal postural adjustments with freedom of movement.

(b) *Social grouping.* Nonhuman primates must be housed in primary enclosures with compatible members of the same species or with compatible members of other nonhuman primate species, in pairs, family groups, or other compatible social groupings, unless the attending veterinarian determines that doing so would endanger the health, safety, and well-being of the nonhuman primates. Compatibility of nonhuman primates must be determined in accordance with generally accepted professional practices and actual observation to ensure that the nonhuman primates are in fact compatible. Individually housed nonhuman primates must be able to see and hear nonhuman primates of their own or compatible species, unless the attending veterinarian determines that it would endanger their health, safety, and well-being. If, in accordance with these regulations, this contact is not provided, the isolated individually housed nonhuman primates must have positive physical contact or other interaction with their keeper or other familiar and knowledgeable person for at least one hour each day.

(c) *Minimum space and physical environment requirements.* Primary enclosures must meet the applicable minimum space and physical environment requirements provided in this subpart. These minimum space requirements must be met even if perches, swings, ledges, or other suspended fixtures are placed in the enclosure.

(1) Research facilities; federal research facilities.

(i) The minimum space that must be provided to *each* nonhuman primate, whether housed individually or with other nonhuman primates, is determined by the typical weight of animals of its species, except for brachiating species,[2] in accordance with the following table:[3]

[2] The different species of nonhuman primates are divided into seven weight groups for determining minimum space requirements, except that all brachiating species of any weight are grouped together since they require additional space to engage in species-typical behavior. The grouping provided is based upon the typical weight for various species and not on changes associated with obesity, aging, or pregnancy. These conditions will not be considered in determining a nonhuman primate's weight group unless the animal is obviously unable to make normal postural adjustments and movements within the primary enclosure. Different species of prosimians vary in weight and should be grouped with their appropriate weight group. They have not been included in the weight table since different species typically fall into different weight groups. Infants and juveniles of certain species are substantially lower in weight than adults of those species and require the minimum space requirements of lighter weight species unless the animal is obviously unable to make normal postural adjustments and movements within the primary enclosure.

[3] The following are examples of the kinds of nonhuman primates typically included in each group:

Group 1—marmosets, tamarins, and infants (up to 6 months of age) of various species.

Group 2—capuchins, squirrel monkeys and similar size species, and juveniles (6 months to 3 years of age) of various species.

Group 3—macaques and African species.

Group 4—male macaques and large African species.

Group 5—baboons and nonbrachiating species larger than 33.0 lbs. (15 kg.).

Group 6—great apes up to 88.0 lbs. (40 kg.) and brachiating species.

Group 7—great apes >88.0 lbs. (40 kg.).

Group	Weight		Floor Area/Animal		Height	
	lbs.	(kg.)	ft.^{2}	(m^2)	in.	(cm.)
1	2.2	(1)	1.6	(0.15)	20	(50.8)
2	2.2–6.6	(1–3)	3.0	(0.28)	30	(76.2)
3	6.6–20.0	(3–10)	4.3	(0.40)	30	(76.2)
4	20.0–33.0	(10–15)	6.0	(0.56)	32	(81.28)
5	33.0–55.0	(15–25)	8.0	(0.74)	36	(91.44)
6	55.0–88.0	(25–40)	25.1	(2.33)	84	(213.36)
7	>88.0	(>40)	50.0	(4.65)	84	(213.36)

(ii) Primary enclosures not precisely meeting the floor area and height requirements provided in paragraph (c)(1)(i) of this section but that do provide nonhuman primates with a sufficient volume of space and the opportunity to express species-typical behavior, such as primate pole housing, may be used with written permission from the Administrator. An application for permission must demonstrate in written and photographic detail why the primary enclosure should be allowed. Nonhuman primates housed in these types of primary enclosures that are also designed and constructed in a manner that provides for their psychological well-being by allowing exercise and social interaction may be excused from the release period required in § 3.81(a)(3) if it is sufficiently justified in the application. The Administrator may deny the application if he or she determines that granting it will be detrimental to the health and psychological well-being of the nonhuman primates to be housed in the primary enclosure. The Administrator will advise the research facility of his or her decision in writing.

(iii) Environmental enrichments must be provided in accordance with § 3.81.

(2) *Dealers.* (i) Individual nonhuman primates that are not part of an established pair, family, or other social group may be housed individually if the

attending veterinarian determines that it is necessary for their health, safety, and well-being. Except as provided in paragraph (c)(2)(v) of this section, the minimum space that must be provided to each nonhuman primate housed individually is twice the minimum floor area and twice the minimum height (up to a maximum height of 84 inches) that research facilities are required to provide in accordance with paragraph (c)(1) of this section.

(ii) Except when nonhuman primates must be individually housed for the purposes set forth in paragraph (c)(2)(v) of this section, established pairs, families, or other social groups of nonhuman primates must be maintained together in a primary enclosure. Primary enclosures used to house nonhuman primates in pairs, families, and other social groups must satisfy the minimum space requirements provided in paragraph (c)(1) of this section, in accordance with the requirements of paragraph (d) of this section for housing more than 1 nonhuman primate in a primary enclosure.

(iii) Dealers must enrich the environment in primary enclosures to promote the psychological well-being of nonhuman primates. This can be done by, among other things:

(A) Providing items such as perches, swings, mirrors, or other cage complexities that enable nonhuman primates to engage in activities typical of their age and species;

(B) Providing playthings and manipulative objects; and

(C) Using foraging or task-oriented feeding methods.

(iv) Multiple enrichments of the environment must be provided for each animal housed in a primary enclosure. The nature of the enrichments provided must be appropriate for the species of nonhuman primates housed in the enclosure.

(v) Dealers may meet the minimum space requirements required of research facilities in paragraph (c)(1) of this section, instead of the space requirements provided in paragraph (c)(2)(i) of this section, in the following instances:

(A) When holding a nonhuman primate for required federal, state, or local quarantine periods;

(B) When a nonhuman primate is receiving veterinary care as directed by the attending veterinarian; or

(C) While transporting a nonhuman primate to or from an auction sale and while holding it at the sale.

(3) *Exhibitors.* Nonhuman primates are grouped by species into the following 7 groups for purposes of determining the minimum space and environment requirements that exhibitors must provides:

Nonhuman Primate Group	Type	Example
1	Prosimian Primates	Tarsiers, Galagos, Pottos, Lorises, Lemurs, Mouse Lemurs Avahis, Indris, Sifakas, and Aye-ayes
2	Marmosets and Tamarins	Marmosets, Tamarins, and Callimico
3	Other New World Monkeys	Howler Monkeys, Owl Monkeys, Spider Monkeys, Woolly Spider Monkeys, Uakaris, Titi Monkeys, Capuchins, Saki Monkeys, Woolly Monkeys, and Squirrel Monkeys
4	Langurs and Colobines	Proboscis Monkey, Langur, Colobus Monkey
5	Other Old World Monkeys	Baboons, Drills, Mandrills, Macaques, Guenons, Mangabeys, Talapoins, Patas Monkeys and Swamp Monkeys
6	Lesser Apes	Gibbons and Siamang
7	Great Apes	Orangutans, Chimpanzees, Gorillas

The minimum space and environmental enrichments that must be provided to each grouping of nonhuman primates housed in a primary enclosure must be appropriate for the species housed, as provided in this paragraph, and in accordance with the following chart:

Nonhuman Primate Group	Species/Type	Minimum No. Primates Per Enclosure	Minimum Primary Enclosure Size (Length, Width, Height)	Shelter Dens/Nest Boxes	Enclosure Furnishings or Equipment
Prosimians	Tarsiers	Pair	1m L × 1m W × 2m H (3.28ft) × (3.28ft) × (6.56ft).	12.7cm L × 12.7 cm W × 12.7cm H (5.0in) × (5.0in) × (5.0in) for each adult in upper half of exhibit.	1, 2, 3
	Loris & Galago: Smaller species.	Pair or family group	1.5cm L × 1.5cm W × 1.5cm H (4.92ft) × (4.92ft) × (4.92ft).	12.7cm L × 12.7cm W × 12.7cm H (5in) × (5in) × (5in) for each adult in upper half of exhibit.	1, 3
	Larger species		3m L × 3m W × 3m H (9.84ft) × (9.84ft) × (9.84ft).	76.2cm L × 47.2cm W × 47.7cm H (30in) × (18.6in) × (18.8in).	
	Lemurs	Pair	1.52m L × 1.52m W × 1.83m H (4.98ft) × (4.98ft) × (6.0ft).	0.46m L × 0.46m W × 0.46m H (1.5ft) × (1.5ft) × (1.5ft) for each adult and in upper half of exhibit.	1, 2

Nonhuman Primate Group	Species/Type	Minimum No. Primates Per Enclosure	Minimum Primary Enclosure Size (Length, Width, Height)	Shelter Dens/Nest Boxes	Enclosure Furnishings or Equipment
	Mouse Lemurs	Pair	1.22m L × 1.22m W × 1.22m H	10.,16cm L × 10.16cm W × 10.16cm H.	1
			(4.0ft) × (4.0ft) × (4.0ft)	(4.0in) × (4.0in) × (4.0in) for each adult and in upper half of exhibit..	
	Indris	Pair or family group	5m L × 5m W × 5m H	One shelter for all.	1, 2, 4
	Avahis		(167.4ft) × (16.4ft) × (16.4ft)		
	Sifakas				
	Aye-Ayes	Pair	4m L × 3m W × 3m H	76.2cm L × 47.7cm W × 47.7cm H	4, 7
			(13.12ft) × (9.8ft) × (9.8ft)	(2.5ft) × (1.5ft) × (1.5ft) for each adult and in upper half of exhibit..	
Marmosets	Smaller < 500g	Pair	0.91m L × 0.91m W × 1.83m H	One shelter for all.	1, 2, 5
Tamarins			(3ft) × (3ft) × (6ft)	*Note:* Minimum temperature of 70°F.	
Callimico	Larger > 500g		1.22m L × 2.44m W × 2.44m H		
			(4ft) × (8ft) × (8ft)		
Other New World Monkeys.	Titis, Owl, & Squirrel	Pair	2m L × 2m W × 2m H (6.56ft) × (6.56ft) × (6.56ft).	One shelter for all.	1, 2, 5, 6
		Up to 6	2.5m L × 2.5m W × 2.5m H (8.2ft) × (8.2ft) × (8.2ft).	*Note:* Sakis, Titis, & Owls are Monogamous..	
	Capuchin	Pair	2.5m L × 2m W × 2m H		
	Ukaris		(8.2ft) × (8.2ft) × (8.2ft)		
	Sakis	Up to 5	4m L × 2.5m W × 2.5m H (13.12ft) × (8.2ft) × (8.2ft).		
	Howler	Pair	3m L × 3m × 3m H		
	Wooly		(9.84ft) × (9.84ft) × (9.84ft)		
	Spider	Over 2	3.5m L × 3.5m W × 3.5m H (11.5ft) × (11.5ft) × (11.5f).		
Langurs, Colobines.	Proboscis, Langur, Colobus.	Pair or family group	Width, length, and height are to be at least 3 times the length from tip of nose to tip of tail for the largest animal.	Two boxes, each one at least 1½ times the length from tip of nose to tip of tail. *Note:* Temperature range should be 70–85°F..	1, 2, 6
Other Old Monkeys (Cercopithecids).	Baboons, Drills, Mandrills, Macaques Guenons, Mangabeys, Talapoins, Patas & Swamp Monkeys.	Pair or family group	Area=54 times the head and body length of the largest adult. Height=8ft minimum (2.44m).	Sufficient shelter for all.	1, 2, 3, 7
Lesser Apes	Gibbons	Pair	4.27m L × 4.27m W × 3.05m H (14ft) × (14ft) × (10ft).	One shelter for all.	1, 2, 8
	Siamangs		4.27m L × 5.48m W × 3.05m H (14ft × (18ft) × (10ft).	*Note:* These species are arboreal brachiators, are monogamous, and are strongly territorial..	
Greater Apes	Pygmy Chimpanzees	Pair	4.27m L × 4.27m W × 3.05m H (14ft) × (14ft) × (10ft).	Shelter for all by individual or group	7, 9, 10, 11
	Chimpanzee	One	4.27m L × 4.27m W × 3.05m H		
	Gorilla		(14ft) × (14ft) × (10ft)		
	Orangutan	Pair	8.54m L × 8.54m W × 3.05m H (28ft) × (28ft) × (10ft) Space should be divided into separate areas or shift cages be available.		

1. Vertical and horizontal branches/poles of suitable size for the species.
2. Elevated perches/resting shelves of sufficient size to hold all primates.
3. Elevated pathways of tree branches/poles/or other material suitable for the species.
4. Multidirectional pathways of branches/poles/or other material of suitable size for the species.
5. Elevated feed and water stations.
6. Visual barriers.
7. Nontoxic hay/straw/leaves/branches/browse for foraging or nesting.
8. Three to four horizontal branches/poles about 2 feet apart throughout exhibit at heights that are greater than the body length of the animal when arms and legs are fully extended.
9. Climbing structures and elevated platforms at least 1 meter (3.28ft) apart and at varying heights.
10. Ropes anchored at each end which are taut enought to prevent being wrapped around an arm or leg.
11. Objects to manipulate such as tires, plastic drums, or "boomer" balls.

(4) *Mobile or traveling animal act exhibitors.* (i) Primary enclosures used to house nonhuman primates that participate daily in acts, shows, or training periods outside of their enclosure must satisfy the minimum space requirements provided in paragraph (c)(1) of this section for research facilities. No enhancements of the primary enclosure environment are required.

(ii) Primary enclosures used to house up to 3 nonhuman primates that are permanently contained in their primary enclosure must provide at least three times the floor space and twice the minimum height (up to a maximum height of 84 inches) required in paragraph (c)(1) of this section for research facilities. The minimum space provided must be increased in accordance with paragraph (d) of this section for each additional 1–3 nonhuman primates housed together in the primary enclosure. The environment in the primary enclosure must be enriched to promote the psychological well-being of the nonhuman primates in a manner that allows them to engage in activities that are typical for their age and species. The environment must be enriched by providing items such as perches, swings, mirrors, or other increased cage complexities; providing playthings or manipulative objects; and by using foraging or task-oriented feeding methods.

(d) Except for nonhuman primates housed by exhibitors in accordance with

paragraphs (c)(3), and as provided in paragraphs (c)(2)(ii) [dealers] and (c)(4)(ii) [mobile or traveling animal act exhibitor] of this section, when more than one nonhuman primate is housed in a primary enclosure, the minimum space requirement for the enclosure is the sum of the minimum floor area space requirements that must be provided for *each* nonhuman primate housed in the enclosure and double the minimum height requirement for the largest nonhuman primate housed in the enclosure (up to a maximum height of 84 inches).[4]

(e) *Variance from minimum space requirements.*—(1) *Definition.* For the purposes of this subpart, "variance" means the written permission from the Administrator that is required to operate as a licensee or registrant under the Animal Welfare Act without fully complying with the minimum space requirements provided in this subpart. A variance may be limited in scope both as to time and to the primary enclosures covered by it, and will specify the portions of a registrant's or licensee's facilities covered by the variance.

(2) *Who may apply; eligibility.* Registrants and licensees that maintain or handle nonhuman primates, or that have nonhuman primates on the premises or under their control or supervision, and that do not comply with one or more of the minimum space requirements provided in this subpart may apply to the Administrator for a variance. Any housing facilities under construction or in the design and preliminary construction stages on the effective date of these regulations must comply with these standards and are not eligible for a variance, unless the registrant or licensee demonstrates to the Administrator that construction is so nearly complete that a variance is necessary for the registrant or licensee to fully comply with the minimum space requirements.

[4] An example of how to determine the minimum space that must be provided for two nonhuman primates housed together in one primary enclosure would be: Assume a squirrel monkey (Group 2 of paragraph (1)) is housed with a baboon (Group 5 of paragraph (1)). The minimum floor area required would be the Group 2 minimum floor area (3.0 sq. ft.) plus the Group 5 minimum floor area (8.0 sq. ft.), or 11 square feet. The minimum height required would be double the Group 5 minimum height (36 in. ht. × 2—72 in. ht.), since the minimum height required for the largest nonhuman primate housed in the enclosure is doubled.

Assume a second squirrel monkey is added to the same primary enclosure. An additional Group 2 minimum floor area (3.0 sq. ft.) would be added to determine the total minimum floor area space requirement for that primary enclosure. (11 sq. ft. + 3 sq. ft.—14 sq. ft.) The minimum height would not be increased.

(3) *When to apply.* Eligible registrants and licensees requiring a variance in accordance with paragraph (e)(2) must apply to the Administrator within 60 days of the effective date of these regulations.

(4) *Application.* An application for a variance must be in writing and must list in detail each of the minimum space requirements that cannot be complied with, the amount of time necessary for the applicant to come into compliance with the minimum space requirements, the specific reasons why the variance is being requested, the species and number of nonhuman primates that will be affected by the variance, and the estimated cost of compliance. A statement from the attending veterinarian concerning the age and health status of the nonhuman primates affected by the variance and addressing whether the granting of a variance would be detrimental to the affected nonhuman primates must accompany the application. The Administrator may grant the application if he or she determines that it is justified or deny it if he or she determines that it is not justified under the circumstances, or that granting it would be detrimental to the health and psychological well-being of the nonhuman primates affected by the variance. The grant or denial will be in writing. The Administrator may require a report to be submitted by an outside expert to help determine whether a variance would be detrimental to the health and psychological well-being of the nonhuman primates affected. The cost of the report must be paid by the applicant. The applicant may request that the Administrator reconsider his or her decision to deny an application by writing to the Administrator within ten (10) days after the applicant has received the denial. The applicant must explain, in writing, why he or she believes the variance should have been granted. The Administrator will notify the applicant in writing of the final decision as promptly as circumstances allow.

(5) *Duration and extension.* An initial variance may be granted, at the sole discretion of the Administrator, for the period of time the Administrator determines is necessary for the applicant to comply with the minimum space requirements, based upon the facts presented in the application, up to a maximum time of 2 years. The Administrator may grant a single extension of up to 1 year upon written request, if the Administrator determines that it is justified due to unforeseen situations that prevent the registrant or licensee from fully complying during the initial variance period. A written request for an extension must be received by the Administrator at least 60 days before the expiration date of the initial variance. No more than 1 extension will be granted. The grant or denial of an application for an extension will be in writing. The applicant may request that the Administrator reconsider his or her decision to deny an application for extension by writing to the Administrator within ten (10) days after the applicant has received the denial. The applicant must explain, in writing, why he or she believes the extension should have been granted. The Administrator will notify the applicant in writing of the final decision as promptly as circumstances allow. Until a final determination is made, the extension will not be in effect. If the extension is granted on reconsideration, it will be retroactive to the termination date of the initial variance.

(6) *Revocation.* A variance may be revoked by the Administrator at any time if he or she determines that it was obtained in bad faith, that the purpose for which the variance was granted is not being carried out, or that it is detrimental to the health and psychological well-being of the nonhuman primates affected. Revocation of a variance will be in writing and effective upon receipt.

§ 3.81 Additional requirements for research facilities

(a) Research facilities, including federal research facilities, must comply with the following requirements in order to promote the psychological well-being of nonhuman primates:

(1) The physical environment in primary enclosures must be enriched by providing means of expressing species-typical activities. Examples of environmental enrichments include providing perches, swings, mirrors, and other increased cage complexities; providing toys or objects to manipulate; and using foraging or task-oriented feeding methods.

(2) Nonhuman primates must be housed in social groupings in accordance with § 3.80(b).

(3) An individually housed nonhuman primate must be released for a minimum of four hours of exercise and social interaction per week into an area that is at least three times the area and twice the height (up to a maximum height of 84 inches) required for that species in § 3.80(c)(1). Individually housed nonhuman primates may be placed with compatible species for their exercise periods. Nonhuman primates that are

not housed individually and those that are housed individually in a primary enclosure that provides at least twice the volume required for that species in § 3.80(c)(1) do not have to be released for an exercise period.

(4) Research facilities must consult with the attending veterinarian with regard to the following individually housed nonhuman primates and must provide additional environmental enrichments, exercise, and social interaction, in accordance with the instructions of the attending veterinarian:

(i) Infants and juveniles;

(ii) Adults used in research for which the animal care and use procedure does not provide much activity;

(iii) Those that show signs of being in psychological distress through behavior or appearance.

(b) Primate chairs. Nonhuman primates must not be placed in chairs unless it is required by an animal care and use procedure and the Committee approves of it for a particular animal. If the use of chairs is approved for a nonhuman primate, it must be released daily for exercise for at least one continuous hour during the period it is placed in a chair, unless continuous restraint in a chair is required by an animal care and use procedure and approved by the Committee. If continuous restraint is approved for a nonhuman primate it must be released for exercise for at least one hour before it is restrained and for at least one hour after the period of restraint.

(c) Records. Documentation of the release of each nonhuman primate for exercise and social interaction and of additional environmental enrichments that must be provided under paragraph (a)(4) of this section must be kept by the attending veterinarian and is subject to APHIS inspection, and in the case of federal research facilities, to inspection by officials of any federal funding agency.

(d) Exemptions. The attending veterinarian may exempt a particular nonhuman primate from the exercise and social release period required for it under paragraphs (a)(3) and (b) of this section, or restrict its participation in the period, if he or she determines that it is necessary to do so for its health, condition, or psychological well-being due to the physical or psychological condition of the animal. The exemption or restriction must be recorded by the attending veterinarian and the documentation is subject to APHIS inspection, and in the case of federal research facilities, to inspection by officials of any federal funding agency. The attending veterinarian must review the grant of exemption or restriction and observe the animal at least every 30 days to determine whether it is still necessary. All exemptions and restrictions must be included in the Annual Report of the research facility.

Animal Health and Husbandry Standards

§ 3.82 Feeding.

(a) The diet for nonhuman primates must be appropriate for the species, size, age, and condition of the animal, and for the conditions in which the nonhuman primate is maintained, according to generally accepted professional and husbandry practices and nutritional standards. The diet must consist of varied food items. The food must be clean, uncontaminated, wholesome, and palatable to the animals. It must be of sufficient quantity and have sufficient nutritive value to maintain the normal condition and weight of the animal and to meet its normal daily nutrition and vitamin requirements.

(b) The method of feeding nonhuman primates must be varied daily in order to promote their psychological well-being, such as by using task-oriented feeding and allowing them to forage for food.

(c) Nonhuman primates must be fed at least once each day except as otherwise might be required to provide adequate veterinary care. Infant and juvenile nonhuman primates must be fed as often as necessary in accordance with generally accepted professional and husbandry practices and nutritional standards, based upon the animals' age and condition.

(d) Food and food receptacles, if used, must be readily accessible to all the nonhuman primates being fed. If members of dominant nonhuman primate or other species are fed together with other nonhuman primates, multiple feeding sites must be provided. The animals must be observed to determine that all receive a sufficient quantity of food.

(e) Food and food receptacles, if used, must be located so as to minimize any risk of contamination by excreta and pests. Food receptacles must be kept clean and must be sanitized in accordance with the procedures listed in § 3.84(b)(3) of this subpart at least once every 2 weeks. Used food receptacles must be sanitized before they can be used to provide food to a different nonhuman primate or social grouping of nonhuman primates. Measures must be taken to ensure there is no molding, deterioration, contamination, and caking or wetting of food placed in self-feeders.

§ 3.83 Watering.

Potable water must be provided in sufficient quantity to every nonhuman primate housed at the facility. If potable water is not continually available to the nonhuman primates, it must be offered to them at least twice daily for periods of not less than 1 hour each time, unless the attending veterinarian requires otherwise in order to provide adequate veterinary care to the animal. Water receptacles must be kept clean and free of waste of any kind, and must be sanitized in accordance with the methods provided in § 3.84(b)(3) of this subpart at least once every 2 weeks. Used water receptacles must be sanitized before they can be used to provide water to a different nonhuman primate or social grouping of nonhuman primates.

§ 3.84 Cleaning, sanitization, housekeeping, and pest control.

(a) Cleaning of primary enclosures. Excreta and food waste must be removed at least daily from inside each primary enclosure and from underneath it, and more frequently if necessary, to prevent accumulation of feces and food waste, to prevent the nonhuman primates from becoming soiled, and to reduce disease hazards, insects, pests, and odors. When a steam, hosing, flushing, or other method involving water is used to clean the primary enclosures, nonhuman primates must be removed during the cleaning to prevent them from being involuntarily wetted or injured. Pans underneath primary enclosures with grill-type floors must also be cleaned at least daily, and as often as necessary to prevent accumulation of feces and food waste, and to reduce disease hazards, pests, insects, and odors. Primary enclosures with hard surfaces must be cleaned every day. Dirt floors and planted areas in primary enclosures must be raked and spot cleaned every day. Perches, bars, and shelves must be kept clean and replaced when worn. If the species of nonhuman primates housed in the primary enclosure engages in scent marking, the primary enclosure must be spot cleaned daily.

(b) Sanitization of primary enclosures and food and water receptacles.

(1) A used primary enclosure must be sanitized in accordance with this section before it can be used to house another nonhuman primate.

(2) Primary enclosures must be sanitized at least once every 2 weeks and as often as necessary to prevent any accumulation of dirt, debris, waste, food waste, excreta, or disease hazard, using one of the methods prescribed in

paragraph (b)(3) of this section. However, if the species of nonhuman primates housed in the primary enclosure engages in scent marking, the primary enclosure must be sanitized at regular intervals determined in accordance with generally accepted professional and husbandry practices.

(3) Hard surfaces of primary enclosures and food and water receptacles must be sanitized using one of the following methods:

(i) Live steam under pressure;

(ii) Washing with hot water (at least 180 °F (82.2 °C)) and soap or detergent, such as in a mechanical cage washer; or

(iii) Washing all soiled surfaces with a detergent solution to remove all organic material and mineral buildup, followed by a safe and effective disinfectant rinse, and then a clean water rinse.

(4) Primary enclosures containing material that cannot be sanitized using the methods provided in paragraph (b)(3) of this section, such as sand, gravel, dirt, grass, or planted areas, must be sanitized by removing the contaminated materials necessary to prevent odors, diseases, pest, insects, and vermin infestation.

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair in order to protect the nonhuman primates from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents, pests, and vermin. Premises must be kept free of accumulations of trash, junk, waste, and discarded matter. Weeds, grass, and bushes must be controlled so as to facilitate cleaning of the premises and pest control.

(d) Pest control. An effective program for control of insects, external parasites affecting nonhuman primates, and birds and mammals that are pests, must be established and maintained so as to promote the health and well-being of the animals and reduce contamination by pests in animal areas.

§ 3.85 Employees.

Every person subject to the Animal Welfare regulations maintaining nonhuman primates must have enough employees to carry out the level of husbandry practices and care required in this subpart. The employees who provide husbandry practices and care, or handle animals, must be supervised by an animal caretaker who has the knowledge, background, and experience in proper husbandry and care of nonhuman primates to supervise others. The employer must be certain that the supervisor can perform to these standards.

§ 3.86 Social grouping and separation.

(a) Nonhuman primates housed in the same primary enclosure must be grouped with compatible members of the same or other nonhuman primate species, or with other compatible animal species, with the following restrictions:

(1) If a nonhuman primate exhibits vicious or overly aggressive behavior it must be housed separately;

(2) Nonhuman primates under quarantine or treatment for a communicable disease must be housed separately from other nonhuman primates and susceptible species of animals to minimize the risk of spread of the disease; and

(3) Nonhuman primates may not be housed with other species of primates or animals unless they are compatible, do not compete for food and shelter, and are not hazardous to the health and well-being of each other;

(b) Families must be housed together and compatible groups must remain constant.

Transportation Standards

§ 3.87 Consignments to carriers and intermediate handlers.

(a) Carriers and intermediate handlers must not accept a nonhuman primate for transport in commerce more than 4 hours before the scheduled departure time of the primary conveyance on which the animal is to be transported. However, a carrier or intermediate handler may agree with anyone consigning a nonhuman primate to extend this time by up to 2 hours.

(b) Carriers and intermediate handlers must not accept a nonhuman primate for transport in commerce unless they are provided with the name, address, phone number, and telex number, if applicable, of the consignee.

(c) Carriers and intermediate handlers must not accept a nonhuman primate for transport in commerce unless written instructions concerning in transit food and water requirements for each nonhuman primate in the shipment are securely attached to the outside of its primary enclosure in a manner that makes them easily noticed and read.

(d) Carriers and intermediate handlers must not accept a nonhuman primate for transport in commerce unless the consignor certifies in writing to the carrier or intermediate handler that the nonhuman primate was offered food during the 12 hours and water during the 4 hours before delivery to the carrier or intermediate handler, and specifies the date and time the nonhuman primate was last offered food and water. A copy of the certification must accompany the nonhuman primate to its destination and must include the following information for each nonhuman primate:

(1) The consignor's name and address;

(2) The species of nonhuman primate;

(3) A statement by the consignor certifying that each nonhuman primate continued in the primary enclosure was offered food during the 12 hours and water during the 4 hours before delivery to the carrier or intermediate handler, and the date and time food and water was last offered; and

(4) The consignor's signature and the date and time the certification was signed.

(e) Carriers and intermediate handlers must not accept a nonhuman primate for transport in commerce unless the primary enclosure meets the requirements of § 3.88 of this subpart, or the consignor certifies in writing to the carrier or intermediate handler that the primary enclosure meets the requirements of § 3.88 of this subpart. Even if the consignor provides this certification, a carrier or intermediate handler must not accept a nonhuman primate for transport if the primary enclosure is obviously defective or damaged and cannot reasonably be expected to safely and comfortably contain the nonhuman primate without suffering or injury. A copy of the certification must accompany the nonhuman primate to its destination and must include the following information for each primary enclosure:

(1) The consignor's name and address;

(2) The number of nonhuman primates contained in the primary enclosure;

(3) The species of nonhuman primate contained in the primary enclosure;

(4) A statement by the consignor certifying that each primary enclosure in the shipment meets the USDA standards for primary enclosures contained in § 3.88 of this subpart; and

(5) The consignor's signature and the date the certification was signed.

(f) Carriers and intermediate handlers must not accept a nonhuman primate for transport in commerce unless their holding area and cargo facilities meet the minimum temperature requirements provided in §§ 3.91 and 3.92 of this subpart, or unless the consignor provides them with a certificate signed by a veterinarian and dated no more than 10 days before delivery of the animal to the carrier or intermediate handler for transport in commerce, certifying that the animal is acclimated to temperatures lower than those required in §§ 3.91 and 3.92 of this subpart. Even if the carrier or intermediate handler receives this

certification, the temperatures the nonhuman primate is exposed to while in the carrier's or intermediate handler's custody must not be lower than the minimum temperature specified by the veterinarian in accordance with paragraph (f)(3) of this section, and must be reasonably within the generally and professionally accepted temperature range for the nonhuman primate, as determined by the veterinarian, considering its age, condition, and species. A copy of the certification must accompany the nonhuman primate to its destination and must include the following information for each primary enclosure:

(1) The consignor's name and address;

(2) The number of nonhuman primates contained in the primary enclosure;

(3) The species of nonhuman primate contained in the primary enclosure;

(4) A statement by a veterinarian that to the best of his or her knowledge, each of the nonhuman primates contained in the primary enclosure is acclimated to air temperatures lower than 45 °F (7.2 °C), but not lower than a minimum temperature specified on the certificate based on the generally and professionally accepted temperature range for the nonhuman primate considering its age, condition, and species; and

(5) The veterinarian's signature and the date the certification was signed.

(g) When a primary enclosure containing a nonhuman primate has arrived at the animal holding area of a terminal facility after transport, the carrier or intermediate handler must attempt to notify the consignee upon arrival and at least once in every 6-hour period after arrival. The time, date, and method of each attempted notification and the actual notification of the consignee, and the name of the person who notifies or attempts to notify the consignee must be written on the carrier's or intermediate handler's copy of the shipping document and on the copy that accompanies the primary enclosure. If the consignee cannot be notified within 24 hours after the nonhuman primate has arrived at the terminal facility, the carrier or intermediate handler must return the animal to the consignor or to whomever the consigner designates. If the consignee is notified of the arrival and does not take physical delivery of the nonhuman primate within 48 hours after arrival of the nonhuman primate, the carrier or intermediate handler must return the animal to the consignor or to whomever the consignor designates. The carrier or intermediate handler must continue to provide proper care, feeding, and housing to the nonhuman primate, and maintain the nonhuman primate in accordance with generally accepted professional and husbandry practices until the consignee accepts delivery of the nonhuman primate or until it is returned to the consignor or to whomever the consignor designates. The carrier or intermediate handler must obligate the consignor to reimburse the carrier or intermediate handler for the cost of return transportation and care.

§ 3.88 Primary enclosures used to transport nonhuman primates.

Any person subject to the Animal Welfare regulations must not transport or deliver for transport in commerce a nonhuman primate unless it is contained in a primary enclosure, such as a compartment, transport cage, carton, or crate, and the following requirements are met:

(a) *Construction of primary enclosures.* Primary enclosures used to transport nonhuman primates may be connected or attached to each other and must be constructed so that:

(1) The primary enclosure is strong enough to contain the nonhuman primate securely and comfortably and to withstand the normal rigors of transportation;

(2) The interior of the enclosure has no sharp points or edges and no protrusions that could injure the animal contained in it;

(3) The nonhuman primate is at all times securely contained within the enclosure and cannot put any part of its body outside the enclosure in a way that could result in injury to the animal, to handlers, or to persons or animals nearby;

(4) The nonhuman primate can be easily and quickly removed from the enclosure in an emergency;

(5) The doors or other closures that provide access into the enclosure are secured with animal-proof devices that prevent accidental opening of the enclosure, including opening by the nonhuman primate;

(6) Unless the enclosure is permanently affixed to the conveyance, adequate devices such as handles or handholds are provided on its exterior, and enable the enclosure to be lifted without tilting it, and ensure that anyone handling the enclosure will not come into physical contact with the animal contained inside;

(7) Any material, treatment, paint, preservative, or other chemical used in or on the enclosure is nontoxic to the animal and not harmful to the health or well-being of the animal;

(8) Proper ventilation is provide to the nonhuman primate in accordance with paragraph (c) of this section;

(9) Ventilation openings are covered with bars, wire mesh, or smooth expanded methal having air spaces; and

(10) The primary enclosure has a solid, leak-proof bottom, or a removable, leak-proof collection tray under a slatted or wire mesh floor that prevents seepage of waste products, such as excreta and body fluids, outside of the enclosure. If a slatted or wire mesh floor is used in the enclosure, it must be designed and constructed so that the animal cannot put any part of its body between the slats or through the holes in the mesh. It must contain enough previously unused litter to absorbe and cover excreta. The litter must be of a suitably absorbent material that is safe and nontoxic to the nonhumane primate and is appropriate for the species transported in the primary enclosure.

(b) *Cleaning of primary enclosures.* A primary enclosure used to hold or transport nonhuman primates in commerce must be cleaned and sanitized before each use in accordance with the methods provided in § 3.84(b)(3) of this subpart.

(c) *Ventilation.* (1) If the primary enclosure is moveable, ventilation openings must be constructed in one of the following ways:

(i) If ventilation openings are located on two opposite walls of the primary enclosure, the openings on each wall must be at least 30 percent of the total surface areas of the wall and be located above the midline of the enclosure; or

(ii) If ventilation openings are located on all four walls of the primary enclosure, the openings of every wall must be at least 20 percent of the total surface area of the wall and be located above the midline of the enclosure.

(2) Unless the primary enclosure is permanently affixed to the conveyance, projecting rims or similar devices must be located on the exterior of each enclosure wall having a ventilation opening, in order to prevent obstruction of the openings. The projecting rims or similar devices must be large enough to provide a minimum air circulation space of 0.75 inches (1.9 centimeters) between the primary enclosure and anything the enclosure is placed against.

(3) If a primary enclosure is permanently affixed to the primary conveyance so that there is only a front ventilation opening for the enclosure, the primary enclosure must be affixed to the primary conveyance in such a way that the front ventilation opening cannot be blocked, and the front ventilation opening must open directly to an unobstructed aisle or passageway inside of the conveyance. The ventilation opening must be at least 90 percent of

the total area of the front wall of the enclosure, and must be convered with bars, wire mesh, or smooth expanded metal having air spaces.

(d) *Compatibility.* (1) Only one live nonhumane primate can be transported in a primary enclosure, except as follows:

(i) A mother and her nursing infant may be transported together;

(ii) An established male-female pair or family group may be transported together, except that a female in estrus must not be transported with a male nonhuman primate;

(iii) A pair of juveniles of the same species that have not reached puberty may be transported together.

(2) Nonhuman primates of different species must not be transported in adjacent or connecting primary enclosures.

(e) *Space requirements.* Primary enclosures used to transport nonhuman primates must be large enough so that each animal contained in the primary enclosure has enough space to turn around freely in a normal manner and to sit in an upright, hands down position without its head touching the top of the enclosure. However, certain larger species may be restricted in their movements, in accordance with professionally accepted standards of care, when greater freedom of movement would be dangerous to the animal, its handler, or to other persons.

(f) *Marking and labeling.* Primary enclosures, other than those that are permanently affixed to a conveyance, must be clearly marked in English on the top and on one or more sides with the words "Wild Animals" or "Live Animals," "Do Not Tip," and "This Side Up," in letters at least 1 inch (2.5 cm.) high, and with arrows or other markings to indicate the correct upright position of the primary enclosure. Permanently affixed primary enclosures must be clearly marked in English with the words "Wild Animals" or "Live Animals," in the same manner.

(g) *Accompanying documents and records.* Shipping documents that must accompany shipments of nonhuman primates may be held by the operator of the primary conveyance, for surface transportation only, or must be securely attached in a readily accessible manner to the outside of any primary enclosure that is part of the shipment, in a manner that allows them to be detached for examination and securely reattached, such as in a pocket or sleeve. Instructions for food and water and for administration of drugs, medication, and other special care must be attached to each primary enclosure in a manner that makes them easy to notice, to detach for examination, and to reattach securely.

§ 3.89 Primary conveyances (motor vehicle, rail, air, and marine).

(a) The animal cargo space of primary conveyances used to transport nonhuman primates must be designed, constructed, and maintained in a manner that at all times protects the health and well-being of the animals transported in it, ensures their safety and comfort, and prevents the entry of engine exhaust from the primary conveyance during transportation.

(b) The animal cargo space must have a supply of air that is sufficient for the normal breathing of all the animals being transported in it.

(c) Each primary enclosure containing nonhuman primates must be positioned in the animal cargo space in a manner that provides protection from the elements and that allow each nonhuman primate enough air for normal breathing.

(d) During air transportation, the ambient temperature inside a primary conveyance used to transport nonhuman primates must be maintained at a level that ensures the heath and well-being of the species housed, in accordance with generally accepted professional and husbandry practices, at all times a nonhuman primate is present.

(e) During surface transportation, the ambient temperature inside a primary conveyance used to transport nonhuman primates must be maintained between 45 °F (7.2 °C) and 85 °F (30 °C) at all times a nonhuman primate is present.

(f) A primary enclosure containing a nonhuman primate must be placed far enough away from animals that are predators or natural enemies of nonhuman primates, whether the other animals are in primary enclosures or not, so that the nonhuman primate cannot touch the other animals, see them or smell them.

(g) Primary enclosures must be positioned in the primary conveyance in a manner that allows the nonhuman primates to be quickly and easily removed from the primary conveyance in an emergency.

(h) The interior of the animal cargo space must be kept clean.

(i) Nonhuman primates must not be transported with any material, substance (e.g., dry ice), or device in a manner that may reasonably be expected to harm the nonhuman primates or cause inhumane conditions, unless proper precaution is taken to prevent the injury or inhumane conditions.

§ 3.90 Food and water requirements.

(a) Each nonhuman primate that is 1 year of age or more must be offered food [5] at least once every 24 hours. Each nonhuman primate that is less than 1 year of age must be offered food at least once every 12 hours. These time periods apply to dealers, exhibitors, and research facilities, including federal research facilities, who transport nonhuman primates in their own primary conveyances, starting from the time the nonhuman primate was last offered food before transportation was begun. These time periods apply to carriers and intermediate handlers starting from the date and time stated on the certification provided under § 3.87(d). Each nonhuman primate must be offered food within 12 hours before being transported in commerce. Consignors who are subject to the Animal Welfare regulations must certify that each nonhuman primate was offered food within the 12 hours preceding delivery of the nonhuman primate to a carrier or intermediate handler for transportation in commerce, and must certify the date and time of the feeding, in accordance with § 3.87(d).

(b) Each nonhuman primate must be offered potable water during the 4 hours immediately preceding the beginning of its transportation in commerce, and every 12 hours thereafter. This time period applies to dealers, exhibitors, and research facilities, including federal research facilities, who transport nonhuman primates in their own primary conveyances, starting from the time the nonhuman primate was last offered potable water before being transported in commerce. This time period applies to carriers and intermediate handlers starting from the date and time stated on the certification provided under § 3.87(d). Consignors who are subject to the Animal Welfare regulations must certify that each nonhuman primate was offered potable water within 4 hours before being transported in commerce, and must certify the date and time the water was offered, in accordance with § 3.87(d).

(c) Any dealer, exhibitor, or research facility, including a federal research facility, offering a nonhuman primate to a carrier or intermediate handler for transportation in commerce must securely attach to the outside of the primary enclosure used for transporting the nonhuman primate, written instructions for the in-transit food and

[5] Proper food for purposes of this section is described in § 3.82 of this subpart, with the necessities and circumstances of the mode of travel taken into account.

water requirements of the nonhuman primate(s) contained in the enclosure. The instructions must be attached in a manner that makes them easily noticed, detached and returned to the enclosure.

(d) Food and water receptacles must be securely attached inside the primary enclosure and placed so that the receptacles can be filled from outside of the enclosure without opening the door. Food and water receptacles must be designed, constructed, and installed so that a nonhuman primate cannot leave the primary enclosure through the food or water opening.

§ 3.91 Care in transit.

(a) Surface transportation (ground and water). Any person subject to the Animal Welfare regulations transporting nonhuman primates in commerce must ensure that the operator of the conveyance or a person accompanying the operator of the conveyance observes the nonhuman primates as often as circumstances allow, but not less than once every 4 hours, to make sure that they have sufficient air for normal breathing, that the ambient temperature is within the limits provided in § 3.89(d), and that all other applicable standards of this subpart are being complied with. The regulated person transporting the nonhuman primates must ensure that the operator or the person accompanying the operator determines whether any of the nonhuman primates are in obvious physical distress, and obtains any veterinary care needed for the nonhuman primates at the closest available veterinary facility.

(b) *Air transportation.* During air transportation of nonhuman primates, it is the responsibility of the carrier to observe the nonhuman primates as frequently as circumstances allow, but not less than once every 4 hours if the animal cargo area is accessible during flight. If the animal cargo area is not accessible during flight, the carrier must observe the nonhuman primates whenever they are loaded and unloaded and whenever the animal cargo space is otherwise accessible to make sure that the nonhuman primates have sufficient air for normal breathing, that the ambient temperature is within the limits provided in § 3.89(d), and that all other applicable standards of this subpart are being complied with. The carrier must determine whether any of the nonhuman primates is in obvious physical distress, and arrange for any needed veterinary care for the nonhuman primates as soon as possible.

(c) If a nonhuman primate is obviously ill, injured, or in physical distress, it must not be transported in commerce, except to receive veterinary care for the condition.

(d) During transportation in commerce, a nonhuman primate must not be removed from its primary enclosure unless it is placed in another primary enclosure or a facility that meets the requirements of § 3.80 or § 3.88 of this subpart. Only persons who are experienced and authorized by the shipper, or authorized by the consignor or the consignee upon delivery, if the animal is consigned for transportation, may remove nonhuman primates from their primary enclosure during transportation in commerce.

(e) The transportation regulations contained in this subpart must be complied with until the nonhuman primate reaches its final destination, or until the consignee takes physical delivery of the animal if the animal is consigned for transportation.

§ 3.92 Terminal facilities.

(a) *Placement.* Any persons subject to the Animal Welfare regulations must not commingle shipments of nonhuman primates with inanimate cargo or with other animals in animal holding areas of terminal facilities. Nonhuman primates must not be placed near any other animals, including other species of nonhuman primates, and must not be able to touch or see any other animals, including other species of nonhuman primates.

(b) *Cleaning, sanitization, and pest control.* All animal holding areas of terminal facilities must be cleaned and sanitized in a manner prescribed in § 3.84(b)(3) of this subpart, as often as necessary to prevent an accumulation of debris or excreta and to minimize vermin infestation and disease hazards. Terminal facilities must follow an effective program in all animal holding areas for the control of insects, ectoparasites, and birds and mammals that are pests of nonhuman primates.

(c) *Ventilation.* Air, preferably fresh air, must be provided in any animal holding area in a terminal facility containing nonhuman primates by means of windows, doors, vents, or air conditioning. The air must be circulated by fans, blowers, or air conditioning so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans, vents, fans, blowers, or air conditioning, must be used in any animal holding area containing nonhuman primates when the ambient temperature is 75 °F (23.9 °C) or higher.

(d) *Temperature.* The ambient temperature in an animal holding area containing nonhuman primates must not fall below 45 °F (7.2 °C) or rise above 85 °F (29.5 °C) at any time nonhuman primates are present. The ambient temperature must not rise above 75 °F (23.9 °C) for more than four consecutive hours at any time nonhuman primates are present. The ambient temperature must be measured in the animal holding area by the carrier, intermediate handler, or a person transporting nonhuman primates who is subject to the Animal Welfare regulations, out side any primary enclosure containing a nonhuman primate at a point not more than 3 feet (0.91 m.) away from an outside wall of the primary enclosure, on a level that is even with the enclosure and approximately midway up the side of the enclosure.

(e) *Shelter.* Any person subject to the Animal Welfare regulations holding a nonhuman primate in an animal holding area of a terminal facility must provide the following:

(1) Shelter from sunlight and extreme heat. Shade must be provided that is sufficient to protect the nonhuman primate from the direct rays of the sun.

(2) Shelter from rain or snow. Sufficient protection must be provided to allow nonhuman primates to remain dry during rain, snow, and other precipitation.

(f) *Duration.* The length of time any person subject to the Animal Welfare regulations can hold a nonhuman primate in an animal holding area of a terminal facility upon arrival is the same as that provided in § 3.87(g).

§ 3.93 Handling.

(a) Any person subject to the Animal Welfare regulations who moves (including loading and unloading) nonhuman primates within, to, or from the animal holding area of a terminal facility or a primary conveyance must do so as quickly and efficiently as possible, and must provide the following during movement of the nonhuman primate:

(1) *Shelter from sunlight and extreme heat.* Sufficient shade must be provided to protect the nonhuman primates from the direct rays of the sun. A nonhuman primate must not be exposed to an ambient temperature above 85 °F (29.5 °C) for a period of more than 45 minutes while being moved to or from a primary conveyance or a terminal facility. The temperature must be measured in the manner provided in § 3.92(d) of this subpart.

(2) *Shelter from rain or snow.* Suffcient protection must be provided to allow nonhuman primates to remain dry during rain, snow, and other precipitation.

(3) *Shelter from cold temperatures.* Transporting devices on which nonhuman primates are placed to move them must be covered to protect the animals when the outdoor temperature falls below 45 °F (7.2 °C). A nonhuman primate must not be exposed to an ambient air temperature below 45 °F (7.2 °C) for a period of more than 45 minutes, unless it is accompanied by a certificate of acclimation to lower temperatures as provided in § 3.87(f). The temperature must be measured in the manner provided in § 3.92(d) of this subpart.

(b) Any person handling a primary enclosure containing a nonhuman primate must use care and must avoid causing physical or emotional distress to the nonhuman primate.

(1) A primary enclosure containing a nonhuman primate must not be placed on unattended conveyor belts or on elevated conveyor belts, such as baggage claim conveyor belts and inclined conveyor ramps that lead to baggage claim areas, at any time; except that a primary enclosure may be placed on inclined conveyor ramps used to load and unload aircraft if an attendant is present at each end of the conveyor belt.

(2) A primary enclosure containing a nonhuman primate must not be tossed, dropped, or needlessly tilted, and must not be stacked in a manner that may reasonably be expected to result in its falling. They must be handled and positioned in the manner that written instructions and arrows on the outside of the primary enclosure indicate.

(c) The regulations in this section apply to movement of a nonhuman primate from primary conveyance to primary conveyance, within a primary conveyance or terminal facility, and to or from a terminal facility or a primary conveyance.

Done in Washington, DC, this 7th day of March 1989.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

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